

EPA Reg. No. 2596-179
Vol. 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Date: June 26, 2015

OPP Decision Numbers: 494679, 494678

EPA Reg. Nos.: 2596-179, 2596-178

Product Names: Hartz Reference # 144 (2596-179), Hartz Reference # 143 (2596-178)

EPA Receipt Date: August 25, 2014

EPA Company Number: 2596

Company Name: The Hartz Mountain Corporation

W. Lance H. Hemsarh
Senior Director, R&D
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, New Jersey 07094

Subject: Confirmation of Request to Withdraw an Application

Dear Mr. Hemsarh:

This is to confirm that the Agency has received and processed your request of June 18, 2015 to withdraw the above referenced application. Since we received your request to withdraw this application more than 60 days from the beginning of the decision review period, the Agency has determined that based on the work completed at the time the application was withdrawn, 0% of the amount paid will be refunded. Any future submission related to this action must be submitted as a new application that requires the appropriate fee.

If you have questions concerning this letter, please contact the Pesticide Registration Fee Ombudsperson, Mr. Stephen Schaible at (703) 308-9362.

Sincerely,

A handwritten signature in cursive script that reads "Susan T. Lewis".

Susan Lewis, Director
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

6/17/2015

W. Lance H. Hemsarh
Senior Director, R&D
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, New Jersey 07094

Subject: R340: Efficacy to add new claims
EPA Reg. No.: 2596-179
Product Names: 2596-179 = Hartz Reference # 144
Application Date: 3/18/2015
PRIA Due Date: 7/1/2015
Decision Numbers: 494679 (2596-179)

Dear Mr. Hemsarh;

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

- (a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach

agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Autumn Metzger at 703-305-5314 or Metzger.autumn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Urbanski', with a stylized flourish at the end.

Jennifer Urbanski, PhD, Product Manager 4
Invertebrate and Vertebrate Branch 1 (IVB1)
Registration Division (7505P)
Office of Pesticide Programs

Attachments



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Autumn Metzger

From: Kevin Sweeney, Senior Entomologist

Handwritten signature of Kevin J. Sweeney.

Through: Pesticide Evaluation Review Committee (PERC)

Handwritten initials, possibly "L M W".

Date: June 11, 2015

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

This is a primary review of a rebuttal containing additional efficacy data for this registration action.

DP barcodes: 426808 and 426809

Decision Nos.: 494935 and 494679

Submission Nos: 965920 and 965921

Action code: R340

Product Names: Hartz Reference #143 and #144

EPA Reg. Nos: 2596-178 and 2596-179

Formulation Type: pet spot-ons

Ingredients statement from the label with PC codes includes:

2596-178 = 9.8% fipronil, pc code 129121; 0.25% pyriproxyfen, pc code 129032; and 11.80% (S)-methoprene, pc code 105402.

2596-179 = 9.8% fipronil, pc code 129121; 0.25% pyriproxyfen, pc code 129032; and 11.80% (S)-methoprene, pc code 105402.

Application rate(s) of product: linear dose increments depending upon the weight range as directed by the label.

2596-178 = product dose range from lowest weight class is 0.67 ml (0.023 fl. oz.) (5 lbs) to 4.02 ml (0.136 fl. oz.) (132 lbs.) for the highest weight class.

2596-179 = 1.5 ml (0.051 fl. oz.) applied to cats weighing 3 lbs or more.

Use pattern:

2596-178 is a spot-on for dogs. Apply in a continuous band along the dorsal midline from head to tail.

2596-179 is a spot-on for cats. Apply in a single spot between the shoulder blades on the back of the cat.

OCSP/OPPTS Guidelines: OPPTS 810.3300.

I. Action Requested: Review raw study report data associated with previously cited and reviewed public literature in support of a label amendment. Registrant has requested that the following claims be added to the labels of both products:

“Controls flea infestations on treated cats (and kittens) (&kittens) and prevent infestations in the home.”

“Prevents fleas on treated cats (and kittens) (&kittens) from infesting (reinfesting) your home”

II. Background: The cited literature (nine articles) presented data on a variety of insecticide combinations applied as a spot on to pets. Hartz wishes to use those data to support the above claims, which indicate that applying their product to a pet will control /prevent flea infestations in the home/indoor premises. EPA and Hartz met on October 14, 2014 to discuss these claims and the data needed to support them. Hartz presented a discussion on a new study to EPA and EPA provided input on the study design during the meeting and in a protocol review. Concurrently, Hartz advised EPA that an amendment was pending that included literature to support the above label claims. Instead of relying on the proposed study results, they requested EPA to review the cited published literature to support the claims. EPA advised Hartz that public literature does not stand-alone, but may be used as part of a weight of the evidence approach to supplement a study testing the label claims for control and prevention of fleas in the home.

Subsequently, I reviewed the cited studies on January 8, 2015. I concluded that the cited studies were not sufficient to stand-alone in support of the proposed label claims. My recommendations included “... *The last three studies by Dryden were the most relevant citations but this published literature did not provide the raw data or meet the requirements of GLP. Furthermore, the studies were not conducted with the subject product or with a product that is substantially similar to the subject product.*” In response, Hartz requested – and was granted – an extension of the PRIA date during which time they submitted the study report for literature item 8 below in the attached Appendix.

III. Study Report Review:

Hartz submitted an original study report to supplement the literature cited in Item 8 (see below in Appendix) in order to provide raw data and document study findings. This study was conducted with two registered products (Frontline Plus) containing fipronil (insecticide/adulticide) and S-methoprene (IGR). The subject product contains fipronil (insecticide/adulticide), S-methoprene (IGR), and pyriproxyfen (IGR).

Study Report: VS-USA-28730

MRID49593901. Dryden, M., S. J. Gross, and D. Carithers. 2010. Evaluation of the Efficacy of Frontline Plus for the Control of Flea Populations and Flea-Gender Analysis in Heavily Flea Infested Private Residences and Populations on Naturally Infested Pets in

Tampa, Florida, 13 Years after Fipronil Introduction.

Background: In 1997, one year following product introduction, Frontline Top Spot was assessed in households in the Tampa area. Twelve years later in 2009 this study was performed with Frontline Plus to assess the continued efficacy of fipronil-based products against fleas in the Tampa, Florida area. In the interval between the two studies, retrospective observations were made on retained flea trap samples from household studies, noting that over time, the gender ratio of the flea population tended to shift from predominantly female (or at least 50:50) to predominately male as the flea infestation was being eliminated by on-animal flea control. This study was designed to examine and document these trends on a large scale to help evaluate the success of the flea control program with Frontline. (Note: EPA did issue an EUP for Top Spot in the late 1990s. Much of that data supported current Merial product uses.)

Purpose: determine the impact of appropriate on-animal treatments made to all pets in the household on premise flea populations, flea gender ratio, and on-animal flea burdens.

Materials and Methods:

Location: The study was conducted in Tampa, Florida.

Test substance/Product: fipronil (9.8% w/w)-(S)-methoprene (8.8% w/w) and cats were treated with fipronil (9.8% w/w)-(S)-methoprene (11.8% w/w) (Frontline®Plus for dogs and cats, EPA Reg. Nos. 65331-5 and -4, respectively.)

Test substance/Product application: All pets (dogs and cats) were weighed and Frontline Plus was applied to them according to label directions. Treatments were made on Day 0 and Day 28-30. No other topical or premise treatments were made during the study. More detail provided in treatments descriptions below.

Pest species: cat flea, *Ctenocephalides felis*.

Study design: This was a non-randomized, non-controlled, non-blinded, field study to evaluate the effect (impact) of Frontline Plus on flea emergence/control and flea gender ratios in heavily infested homes in the Tampa area.

Experimental unit: Each household was considered an experimental unit for site assessment of flea emergence and gender ratios. Each animal was considered an experimental unit for on-animal flea assessments.

Animals: the pets (dogs and cats only) used in this study were homeowner owned. (Note: animals had to be qualified for the study as described in the criteria below. It appears that in some cases not all animals qualified.).

Criteria for household inclusion: 29 homes and their respective pets were selected in the Tampa area in the summer of 2009. The inclusion criteria were:

1. Fleas present on pets (minimum of five fleas).
2. Fleas present in home (based upon on at least 5 fleas in KSU intermittent flea light traps).
3. One to four healthy dogs or cats (no more than four).
4. Owner agreed to participate for at least two months.
5. Owners willing to not use any other premise or topical flea treatment during the study.
6. Owner signed consent forms.
7. Owners understood there were no restrictions on the animals regarding exposure to rain, swimming or movement outdoors.
8. No mammalian pets other than dogs or cats in the household.

On-Animal Product Treatments: Dogs were treated topically according to label dosing recommendations; the entire dose was applied on one spot between the shoulder blades for dogs or on the neck for cats. Pets were weighed on Days -1 or 0 to ensure proper dosing. All pets in each enrolled household were treated on Day 0 and then once between Days 28-30. All treatments were applied by study investigators. No other topical or premise flea treatments were used during the study. There were no restrictions on the animals with regard to exposure to rain, swimming or movement outdoors. However, while pet activity was not be restricted, it was recorded. It should be noted that in some homes with multiple dogs and/or cats not all pets qualified for inclusion in the study (fewer than 5 fleas, inability to examine, etc). However, all qualifying and non-qualifying dogs and cats within each enrolled household were still administered weight/species appropriate treatment.

Premise Flea Population Assessment: The numbers of adult fleas emerging in the home were assessed using intermittent light traps¹. Two traps were placed in two distinctly separate rooms/areas for 16 to 24-h for each household assessment period. Light trap site selection was based on where the pet(s) spend most of their time or where owners had observed fleas. Once trap locations were selected for a household, the traps were returned to those same locations for each subsequent counting period. Fleas collected on the adhesive pads of the traps were enumerated and identified as to characteristics (e.g.; fed, unfed, gravid) and as to species. In addition, the gender of fleas collected by light traps for each counting period, for each household, was determined. Environment flea counts were conducted + 1 day on Days 0, 7, 14, 21, then once between Days 28-30, 40-45, and 54-60.

On-Animal Flea Population Assessments: The flea population densities on each pet were estimated using a visual area count methodology (hand counts)². Area counts were performed at five locations on each animal; dorsal midline, tail head, left lateral, right lateral and inguinal region. Area counts were limited to one minute per location and conducted by parting the hair against the lay using both hands until the selected area was covered. Animal flea count estimates were conducted + 1 day on Days 0, 7, 14, 21, then once between Days 28-30, 40-45, and 54-60.

¹ Dryden M, Broce A. Development of a flea trap for collecting newly emerged *Ctenocephalides felis* (Siphonaptera: Pulicidae) in homes. J. Med. Entomol, 30:901-906, 1993.

² Dryden M, Boyer J, Smith V. Techniques for estimating on-animal populations of *Ctenocephalides felis* (Siphonaptera: Pulicidae). J. Med. Entomol. 31:631-624, 1994.

Flea in Premise) Control Assessments: Percentage of control achieved by the flea products were calculated using Geometric Means (GM) and the following formula:

$$\frac{(\text{Day } z \text{ GM Flea trap Counts} - \text{Day } y \text{ GM Flea trap Counts})}{\text{Day } z \text{ GM Flea trap Counts}} \times 100 = \% \text{ control}$$

Where z = Day 0, or the Day with the highest number of fleas collected (red-line homes)

Where y = Day 54-60 (completion date of household)

To determine these geometric means, counts were transformed to the natural logarithm of (count + 1) for calculation.

There were also a subset of homes where an increase in trap counts of at least 125% over Day 0 counts was seen within thirty days following product application on Day 0 (identified in data tables as red-line homes). To address this issue, a second measure for control assessment was performed. In these analysis, using the formula noted, the highest trap total count seen in the first 4 weeks for each household (not necessarily Day 0) was compared to the final trap count for that household. These assessments were performed including all fleas found in the flea traps - fed or unfed. The Geometric Mean Flea Counts of unfed fleas captured in these traps were assessed in the same manner as total fleas captured in the trap. Day 0 to final count, and highest count to final count.

Gender-Ratio Assessments: Fleas collected in traps were assessed for gender throughout the study, noting the arithmetic ratio of female to male fleas (f:m) for each study site. Additionally, arithmetic ratios of only unfed fleas found in the traps were assessed.

On-Animal Flea Counts: On-animal flea count estimates of live adult fleas were transformed to the natural logarithm of (count + 1) for calculation of geometric means by assessment group at each time point. Percent reduction from the control (Day 0) mean were calculated using the formula $[(C - T) / C] \times 100$, where C = geometric mean for the control count (Day 0) count and T = geometric mean for the treated group for each subsequent assessment (Days 0, 7, 14, 21, then once between Days 28-30, 40-45, and 54-60).

Statistics:

Data transformation: As discussed above, this study transformed count data. Count data (e.g., number of individuals or species) are often log-transformed to satisfy parametric test assumptions. Apart from the fact that generalized linear models are better suited in dealing with count data, a log-transformation of counts has the additional quandary in how to deal with zero observations. With just one zero observation (if this observation represents a sampling unit), the whole dataset needs to be "adjusted" by adding a value (usually 1) before transformation.

Flea control/reduction assessment: To compare the reductions in flea counts in traps from Day 0 to Day 54-60 and from "maximum count to Day 54-60, the final count value was subtracted from the starting value, and the difference was transformed to the natural logarithm of (count +

1); if the final count was higher than the initial count, causing a negative "reduction" the difference was defined as equal to zero. A t-test was then performed on the transformed differences with a null hypothesis that the mean difference was equal to zero; 2-sided p-values were reported.

Gender ratio: To compare the sex ratio of all fleas or unfed fleas in traps on Day 6 to that on Day 54-60, a test of two independent proportions was used; 2-sided p-values were reported. Flea counts on the pets were summarized for each site by calculating geometric means for each site and day as described for trap counts; maximum count for each animal or each site was not determined. Geometric means overall and for each type of site were calculated as described for trap counts, with each site having equal weight in the calculation, and percent reduction from Day 0 to Day 54-60 was calculated as described above for trap counts. The p-value for the difference between Day 0 and Day 54-60 flea counts was determined the same as for trap counts.

Study Results:

Data from twenty-seven households were analyzed in these assessments. Premise flea control and flea gender-ratio assessments were calculated based upon the total numbers of fleas found in the flea traps, and separately by the number of unfed fleas present in the flea traps. On animal flea counts were based on total estimates.

The authors presented data from a 60 day EUP-like field study where every animal (dog and/or cat) received two monthly treatments of FrontLine products. The report focused on the impact (measured by % reduction based on geometric mean counts from flea trap collections) of these treatments on premise flea populations in areas most commonly occupied by the pets such as a resting or sleeping site. Second, the effect of these treatments on flea gender ratios and blood feeding was examined. On-animal counts were also reported. Data were presented in table form with raw data reports located in appendices. The authors also provided special consideration to the most heavily infested households where flea counts actually increased at the beginning of the study.

Flea trap counts for the total fleas captured for each collection date were converted to the geometric mean and the percent control was calculated based on the geometric mean counts seen in the traps at Day 0. By the end of the study (Day 54-60), the percent reduction from Day 0 flea trap counts was 89.2%, with homes described as red-line homes (sites where the count increased by >25% within the first 30 days) experiencing 77.3% reduction and normal homes (sites where the count did not rise over 25% within the first 30 days) a 94.9% reduction of flea burdens was seen (Table 2). In all cases, the reductions seen were all statistically significant ($p < 0.05$).

When percent reduction at the end of the study was calculated based upon the geometric mean of the final count against the geometric mean of the highest flea trap burden measured within the first 30 days of the study, the efficacy for all households was 93.3%, with the red-line home reduction at 91.8% and a reduction of 95.1% was seen in the normal homes (Table 2). These reductions too, were all statistically significant ($p < 0.05$). These same assessments were measured, only counting fleas that were unfed and in the traps, excluding any fleas that had taken a blood meal. When measuring reductions from Day 0 for unfed fleas the total was 85.4%, red-

line homes were 69.7% and normal homes were 93.1%. When reductions were measured against the high burden present in the first thirty days, the unfed flea total was 92.5%, red-line homes measured 90.9% and the normal homes were 94.5% (Table 3). Again, all reductions were statistically significant $p < 0.05$).

Table 2. Geometric mean TOTAL flea (<i>Ctenocephalides felis</i>) trap counts and reduction from control (Day 0) and reduction from maximum trap count, from infested households where all dogs and/or cats are treated with FRONTLINE Plus									
	Day 0	Day 7	Day 14	Day 21	Day 28-30	Day 40-45	Day 54-60	% reduction from Day 0	% reduction from maximum trap count [†]
All Homes	135	6.9	9.8	6.8	4	2.8	1.5	89.20%*	93.30%*
-red line homes	11.9	10.5	17.3	10.8	5.1	5.1	2.7	77.30%*	91.80%*
-normal homes	14.9	4.8	6.1	4.6	3.2	1.6	0.8	94.90%*	95.10%*

*Reduction observed was statistically significant ($p < 0.05$)

I reviewed the raw data presented in this study report and calculated the mean flea count for each day for each group of homes as presented in Table 2a below. The % reduction values for all homes is based on a weighted average because there were 12 red line homes and 15 normal homes. The arithmetic means tends to be more sensitive to outliers as evidenced by the data reported in days 40-45 where one home had 267 fleas. The geometric mean provides a measure more like a median value or one of central tendency.

Table 2 a. (Reviewer calculated from raw data). **Arithmetic mean** of TOTAL flea (*Ctenocephalides felis*) trap counts and reduction from control (Day 0) and reduction from maximum trap count, from infested households where all dogs and/or cats are treated with FRONTLINE Plus.

	Day 0	Day 7	Day 14	Day 21	Days 28-30	Days 40-45	Days 54-60	%reduction from Day 0 at days 54-60	% reduction from maximum trap count +
All Homes								83.6	85
-red line homes only (12)	13.25	17.6	29.8	20.58	7.5	26.6***	3.83	72%	70%
-normal homes only (15)	20.26	8.4	8.4	7.6	4.73	2.8	1.6	93%	97%

*** Home # 7 had 267 fleas collected. This home had one pet.

+ Mean highest infestation day through day 30 is 42.5. The highest average infestation count occurred most frequently on Day 14.

Table 3. Geometric mean UNFED flea (Ctenocephalides felis) trap counts and reduction from control (Day 0) and reduction from maximum trap count, from infested households where all dogs and/or cats are treated with FRONTLINE Plus

	Day 0	Day 7	Day 14	Day 21	Day 28-30	Day 40-45	Day 54-60	% reduction from Day 0	% reduction from maximum trap count
All Homes (27)	6.7	3.8	6.3	4.9	2.4	2.4	1.0	85.4%*	92.5%*
-red line homes only (12)	5.8	5.6	12.0	7.9	3.0	4.3	1.7	69.7%*	90.9%*
-normal homes only (15)	7.6	2.7	3.7	3.3	2.0	1.4	0.5	93.1%*	94.5%*

*Reduction observed was statistically significant ($p < 0.05$)

Gender-Ratio Assessments: The total number of fleas captured in the flea traps were assessed for gender and results recorded. Using these data the gender distribution for the total flea population present in the flea traps was assessed. In all homes, at and near initiation of the study, the gender most represented in the capture traps were female fleas, representing 57.9-66.5% of the captured flea population. By the end of the study, the female fleas represented only 42.3% of the captured flea population. This same trend was seen when the houses were segregated into the red-line homes (females representing 67.3%-70.8% in initial counts, falling to 37.0% by study end). These reductions for the total homes and redline homes were statistically significant ($p < 0.05$). Although less apparent, a gender shift was still seen in the normal homes (53% falling to 35.7% by day 40-45, however this percentage rose by study end due in part to the low infestation levels and presence of fed female fleas) (Table 4). However, when these same assessments were measured, counting only fleas that were unfed and in the traps, excluding any fleas that had taken a blood meal, the gender-shift seen on all homes and red-line homes, when counting unfed fleas were statistically significant ($p < 0.05$). In all homes, at and near initiation, the gender distribution for the unfed flea population was weighted toward the female fleas, representing 57.5% to 59.3% of the captured flea population. By the end of the study, female flea representation fell to only 25% of the total population captured. This same trend was more pronounced in the red-line homes, starting out a bit higher at 62%-65.8% and finishing the study a bit lower at 21.4% of the captured population, and slightly less pronounced in the normal homes (53% falling to 33%), and not a significant change ($P = 0.179$) in these homes (Table 5).

Table 4. Percentage of TOTAL flea (Ctenocephalides felis) population comprised by female fleas, in flea traps placed in infested households where all dogs and/or cats were treated with FRONTLINE Plus

	% female fleas of total fleas collected						
	Day 0	Day 7	Day 14	Day 21	Day 28-30	Day 40-45	Day 54-60
All Homes	57.9%	66.5%	50.6%	39.9%	54.1%	42.8%	42.3%*

-red line homes only	67.3%	70.8%	47.8%	36.3%	56.9%	43.8%	37.0%*
-normal homes only	53.0%	58.6%	58.7%	42.4%	47.8%	35.7%	52.0%*

*Reduction observed from Day 0 to Day 54-60, was statistically significant ($p < 0.05$)

Table 5. Percentage of *UNFED* flea (*Ctenocephalides felis*) population comprised by female fleas, in flea traps placed in infested households where all dogs and/or cats were treated with FRONTLINE Plus

	% female fleas of total fleas collected						
	Day 0	Day 7	Day 14	Day 21	Day 28-30	Day 40-45	Day 54-60
All Homes	57.5%	59.3%	44.7%	32.2%	41.4%	40.0%	25.0%*
-red line homes only	65.8%	62.0%	42.5%	26.8%	42.0%	41.2%	21.4%*
-normal homes only	53.4%	53.8%	51.3%	39.0%	40.8%	30.8%	33.3%*

*Reduction observed from Day 0 to Day 54-60, was statistically significant ($p < 0.05$)

On-Animal Flea Counts: Most homes had one pet but some had as many as 3-4. The number of fleas on each pet for each reporting period was reported but whether a pet was a cat or dog was not reported and cat and dog data were not reported separately or analyzed. Instead data were pooled per household for overall calculation of the geometric means for every reporting period for every household. The red-line homes had a total of 23 pets while the normal homes had a total of 27 pets. The all homes data are based on flea collected from a sample size of 50 pets across 27 households. Normal homes showed the most consistent decreases in flea counts after the second product application through 60 days. The red-line homes data were less consistent and the flea load per animal did not differ for some of the animals, which may be due to picking up more fleas outside at these households. Outdoor flea counts were not performed.

Based on the data reported in the appendix, the on-animal flea count estimates for each count date were converted to the geometric mean and the percent control was calculated based on the geometric mean counts seen on animals at Day 0. By the end of the study (Day 54-60), the percent reduction from Day 0 counts for pets from all households in the study was 87.5%. The percent reduction in counts for pets in homes described as red-line homes (sites where the household trap counts increased by 25% within the first 30 days) experiencing 69.7% reduction and normal homes (sites where the trap counts did not rise over 25% within the first 30 days) a 95.0% reduction of on animal flea burdens was seen. All geometric mean count reductions from Day 0 to Day 54-60 were statistically significant ($p < 0.05$). The data show that there was an initial reduction in flea counts on the animals.

IV. Entomologist's Conclusions: The data provided showed that appropriate (monthly) on-animal treatments with Frontline Plus to a total of 50 dogs and cats reduced – but did not eliminate - premise flea populations by 60 days in 27 homes. The treatments results in 82% or greater control of fleas based on arithmetic means and nearly 90% if the assessment is based on the geometric means. Twelve houses reduced fleas by less than these values while 15 houses were better. These treatments also affected the gender ratio of female to male fleas, which resulted in a smaller population of females. On-animal treatments were slightly better than

expected in some homes and excellent in others. Geometric means were calculated in this study because there were no control treatments as these were EUP like trials in human occupied homes where they wanted to eliminate fleas. The products used in this study were not the same as the subject product and neither product contained pyriproxyfen. However, the products used in this test contained an equal or lesser amount of S-methoprene and the same amount of fipronil as the subject product.

V. Entomologist's Recommendations:

1. The data were submitted to amend the subject labels in order to add the following claims:

“Controls flea infestations on treated cats/dogs (and kittens/puppies) (&kittens/puppies) and prevent infestations in the home.”

“Prevents fleas on treated cats/dogs (and kittens/puppies) (&kittens/puppies) from infesting (reinfesting) your home”

The study results indicate that the on-animal product treatments of Frontline Plus:

- Reduced flea premise populations. The data had higher variability in the red-line homes compared to the normal homes.
- Controlled flea infestations on most treated pets. Dogs and cats were not identified but the claim is supported based on the wealth of data on these and related products.

2. Based on the above, the claims “Prevents infestations in the home” and “Prevents fleas from infesting (reinfesting) your home” are not supported. There was considerable variability in the results and mean fleas counts indicate that fleas were not eliminated in the treatments.

APPENDIX - For PERC review I attached the results of the first review below.

Reviews and recommendations from DER dated January 8, 2015.

The registrant submitted nine public literature citations in one MRID that were reviewed as follows on January 8, 2015.

MRID49455301. Volume 1: Supplemental Information - White Paper. "Submission of Laboratory and Field Studies to Confirm Topical Parasiticide Applications Control Pre-Existing In-Home Flea Infestations and Specific Support of In-Home Infestation Control Claims for EPA Reg. Nos. 2596-178 and -179."

The white paper included the following citations. I included the registrants' explanations from their white paper.

"1. Jacobs, D. E., M. J. Hutchinson, D. Ewald-Hamm. 2000. Inhibition of immature *Ctenocephalides felis felis* (Siphonaptera: Pulicidae) development in the immediate environment of cats treated with imidacloprid. *Journal of Medical Entomology* 37 (2): 228-230.

Jacobs et al. (2000) showed that treated cats had transferred sufficient imidacloprid residues to blankets after a 6 hour contact per day, for 5 days. A new blanket was used each week for 4 weeks. Pre-adult flea viability on blankets was reduced by 100%, 84%, 60% and 74% in the 1st, 2nd, 3rd, and 4th week after treatment, respectively.

Entomologist's Conclusion: Unacceptable. The product tested was not similar to the subject product.

2. Jacobs, D. E., M. J. Hutchinson, D. Stanneck. 2001. Accumulation and persistence of flea larvicidal activity in the immediate environment of cats treated with imidacloprid. *Medical and Veterinary Entomology* 15: 342-345.

In another study, Jacobs et al. (2001) used the same test design except for increasing the contact periods to 10 or 20 6-hour blanket contact periods over 2 and 4 weeks, respectively. Results showed that the degree of control was significantly higher after 26 days achieving pre-adult flea control of 100% and 97.4% after 10 or 20 days of blanket exposure, respectively.

Entomologist's Conclusion: Unacceptable. This study was conducted with an imidacloprid based formulation that was not similar to the subject product.

3. Ross, D. H., R. G. Arther, C. von Simson, V. Doyle, M. W. Dryden. 2012. Evaluation of the efficacy of topically administered imidacloprid + pyriproxyfen and orally administered spinosad against cat fleas (*Ctenocephalides felis*): Impact of treated dogs on flea life stages in a simulated home environment. *Parasites & Vectors* 5:192.

Ross et al. (2012) evaluated pre-adult flea control of an orally administered ectoparasiticide versus a topical imidacloprid/pyriproxyfen application. Dogs were housed in pens with floor mats that could be sampled for flea development. Flea infestations were established on-animal 1, 16 and 21 days prior to ectoparasiticide administration. Results showed topical application of the imidacloprid/pyriproxyfen formula resulted in transfer of active ingredients to floor matting. After only 1 week of exposure to treated dogs, floor mat samples provided better than 95% control of adult flea emergence.

While laboratory studies have shown the ability of treated pets to transfer effective amounts of active ingredient within simulated home environments, the same transfer of parasiticide active ingredients under in-home conditions has been demonstrated through field testing.

Entomologist's Conclusion: Unacceptable. This study was conducted with a formulation that contained spinosad.

4. Dryden, M. W., H. Perez, and D. Ulitchny. 1999. Control of fleas on pets and in homes by use of imidacloprid or lufenuron and a pyrethrin spray. JAVMA 215 (1):39-39.

Dryden et al. (1999) investigated existing household flea infestations. The ability for topical parasiticides and oral parasiticides to control in-home infestations was evaluated. It is critical to note that other flea treatments, either applied to the pets or their surrounds, were not used during the study. As well, no restrictions were made regarding exposure of pets to rain, swimming and outdoor activity. Results showed the incidence of fleas on pets and pre-adult flea populations living in the home were reduced by the topical parasiticide application containing imidacloprid. On-animal flea control was achieved within 1 week and in-home infestation was reduced by 86.8% after 4 weeks.

Entomologist's Conclusion: Unacceptable. The product tested was not similar to the subject product as it contained an IGR and adulticides not present in this formulation.

5. Dryden, M. W., J. M. Deneberg, S. Bunch. 2000. Control of fleas on naturally infested dogs and cats and in private residences with topical spot applications of fipronil or imidacloprid. Vet Parasitol. 93: 69-75.

In a follow up study, both fipronil and imidacloprid were evaluated for on-animal and infestation control potential. The same conditions existed for no other pesticide treatments being during the test as well as no restrictions on pets' activities or movement. Results showed on-animal control was achieved for both active ingredients after 1 week. In-home infestation control was as well achieved for both active ingredients exceeding 89.0% after 4 weeks. (Dryden et al. 2000).

Infestation control for both of these studies confirms transfer of active ingredients from treated the in-home environment to control pre-adult flea infestations.

Entomologist's Conclusion: Supplemental. One of the adulticides, fipronil, is present in the formulation at the same level but a complete data set was not provided. Furthermore, the author relied on visual hand counts for assessing flea infestation levels on the animal instead of comb counts.

6. Maynard, L. P. Houffschmitt, and B. Lebreux. 2001. Field efficacy of a 10 percent pyriproxyfen spot-on for the prevention of flea infestations on cats. Journal of Small Animal Practice 42: 491-494.

Maynard et al. (2001) evaluated an IGR only application and the effects it had on in-home flea infestations. Topical application of a 10% pyriproxyfen formula resulted in flea infestation control, measured by 'zero-flea' cats, increasing through the study from 49% control on day 30 to 88% control on day 180. In this study, no restrictions were placed on pets' activities including movement outdoors. It was concluded that appropriately timed topical applications of pyriproxyfen offer a method of flea control in the domestic environment.

Entomologist's Conclusion: Unacceptable. The formulation is not similar to the subject product and amount of pyriproxyfen applied to the cats is not equivalent to the dose to be delivered by the subject product.

7. Dryden, M. W., P. Payne, v. Smith, B. Riggs, J. Davenport, and D. Kobuszewski. 2011a. Efficacy of dinotefuran-pyriproxyfen-permethrin and fipronil-(S)-methoprene topical spot-on formulations to control flea populations in naturally infested pets and private residences in Tampa, FL. Vet. Parasitol. 182:281-286.

Dryden et al. (2011a) repeated an in-home field trial methodology to investigate a dinotefuran/pyriproxyfen/permethrin topical formula versus topically applied fipronil/(S)-methoprene. The fipronil/(S)-methoprene formula provided in-home pre-adult infestation control greater than 88% after 4 weeks. Greater than 96% was achieved after 6 and 8 weeks showing progressive in-home infestation control over time with monthly treatments.

Entomologist's Conclusion: Supplemental. The data from the dinotefuran-pyriproxyfen-permethrin formulation are not relevant to this amendment. The data from the fipronil-methoprene combination products provide supporting data that may be useful in a weight of the evidence approach as the concentration of fipronil and methoprene are similar to the subject product. However, these data cannot stand-alone as they are not complete data sets. The % control at 30 days is less than 90% (Study Table 1).

8. Dryden, M.W., D. Carithers, A. McBride, B. Riggs, L Smith, J. Davenport, V. Smith, P. Payne, S. Gross. 2011b. A comparison of flea control measurement methods for tracking flea populations in highly infested private residences in Tampa FL, following topical treatment of pets with Frontline® Plus(Fipronil/(S)-Methoprene). Intern J. Appl. Res. Vet. Med. 9:356-367.

Dryden et al. (2011b) made an assessment of extremely high in-home flea populations with reinfestation pressure from outside environments. A fipronil/(S)-methoprene formula was tested. Significant flea populations existed in the homes studied. Heavy pressure from outdoor wild animal sources existed. With this constant pressure, over the 60 day study, the percent reduction in unfed adult flea emergence from Day 0 and from maximum trap counts in all homes studied were 85.4% and 92.5%, respectively. Under these excessive test conditions, reduction in flea egg production and the transfer of ectoparasiticide active ingredients in the home by treated pets provided significant infestation control.

Entomologist's Conclusion: Supplemental. The product tested a Merial product containing a similar level of methoprene and fipronil. The data were not collected with the subject product and complete data sets are not available. This citation may be useful in a weight of the evidence approach to supplement a product specific study.

9. Dryden, M. W., P. Payne, V. Smith, M. Chwala, E. Jones, J. Davenport, G. Fadl, M. F. Martinez-Perez de Zeiders, K. Heaney, P. Ford, F. Sun. 2013. Evaluation of indoxacarb and fipronil (S)-methoprene topical spot-on formulations to control flea populations in naturally infested dogs and cats in private residences in Tampa FL. USA. Parasites & Vectors 6:366.

Dryden et al. (2013) also made comparison of formulas containing fipronil/(S)-methoprene versus indoxacarb. The study was done in naturally infested homes. Infestations were noted as the highest ever recorded in Tampa, Florida. Over 2 months, results showed the in-home pre-adult flea infestation control achieved for indoxacarb and fipronil/(S)-methoprene formulas were 97.7% and 84.6%, respectively.

Entomologist's Conclusion: Supplemental for reasons stated for the previous study.

Hartz Conclusions:

"All studies, both laboratory as well as field studies, document in-home pre-adult flea infestation control can be achieved by topical ectoparasiticide treatments. Specifically, laboratory testing under simulated home conditions have substantiated that effective residues of ectoparasiticide formulas do transfer from treated pets to surrounding surfaces. As seen from field trials, those residues in addition to the reduction

in viable eggs being laid on-animal are sufficient to provide pre-adult flea infestation control in the home even under severe adult flea re-infestation pressure.

As for the three field trials discussed above evaluating fipronil/(S)-methoprene topical formulas, and cats were treated with fipronil (9.8% w/w)-(S)-methoprene (8.8% w/w) and fipronil (9.8% w/w) -(S)-methoprene (11.8% w/w), respectively. Results showed flea infestations in the home environment were reduced by over 88% in 4 weeks, by over 92% from peak population counts over 2 months and by over 84% in 2 months. Even with constant heavy pressure from the outside environment, monthly re-applications of a fipronil/(S)-methoprene formula, and no secondary environmental pesticide applications, in-home flea infestations that existed prior to test product application were controlled over a 1 to 2 month period (Dryden et al. 2011a, 2011b, 2013).

These 3 field studies are submitted specifically in support of the claims,

"Controls flea infestations on treated (insert pet) and prevent infestations in the home."


"Prevents fleas on treated (insert pet) from infesting (reinfesting) your home." for EPA registration 2596-178 and 2596-179."

Entomologist's Conclusion: The Dryden et al. studies provide supplemental evidence that transfer of S-methoprene and fipronil may take place in the home. Light trap data were used to survey for fleas but visual hand-counts on the animal were also used. These studies do not meet GLP requirements and were not conducted under an Experimental Use Permit.

Entomologist's Recommendations:

1. The cited literature provides supplemental information on the ability of pet spot-on products to control/prevent fleas in the home environment. However, these citations do not stand alone. A GLP experiment must be conducted to show that this product performs as claimed. Therefore, the proposed claims are not acceptable based on citation of literature.

The last three studies by Dryden were the most relevant citations but this published literature did not provide the raw data or meet the requirements of GLP. Furthermore, the studies were not conducted with the subject product or with a product that is substantially similar to the subject product.

 Receipt for Section 3

S: 965921 Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 2596 THE HARTZ MOUNTAIN CORPORATION

Risk Manager: Registration Division, Risk Management Team 4

Product #: 2596-179 Product Name: HARTZ REFERENCE # 144

Override#

Me Too Section3: No Too Product Name:

Application Date: 18-Mar-2015 OPP Rec'd Date: 23-Mar-2015

Front End Date: 23-Mar-2015 Risk Manager Send Date: 23-Mar-2015

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description: response to product performance DER of 1/8/15: additional data for MRID 49455301

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content Study Des

View/Edit



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

March 18, 2015

FedEx Next Day and via Electronic-mail

Document Processing Desk (Davis/ PM3)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

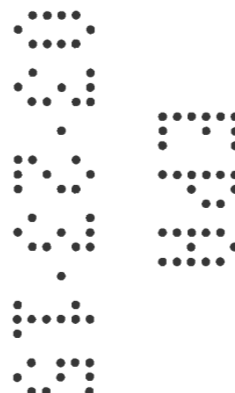
Re: Hartz Reference #144, EPA Reg. No. 2596-179
Response to Product Performance DER, Jan. 8, 2015, Decision No. 494679
Additional data, MRID 49455301, DER item III.8

Dear Ms. Metzger,

Thank you for taking the time to discuss this submission of additional information. The review of the public literature cited above asked for the raw data. Enclosed is the full report we received from Merial supporting the journal article identified as item 8 in the DER cited above. It is the summary and raw data from the study.

In this package please find these items dated March 18, 2015:

1. Cover letter, original
2. Transmittal document
3. Application for Pesticide Registration, EPA Form 8570-1 (3 copies)
4. Certification with Respect to Citation of Data
5. Data Matrix
6. Data Matrix (confidential public copy)
7. No Claim of Confidentiality
8. Study with raw data (3 copies)



March 18, 2015

Page 2

This letter confirms that the article cited in MRID 49455301, item III.8. titled "A comparison of flea control measurement methods for tracking flea populations in highly infested private residences in Tampa FL, ..." from the Inter J. Appl. Res. Vet. Med. 9:356-367 is the retitled version of the study enclosed. The full report with data enclosed "Evaluation of the Efficacy of Frontline Plus for the Control of Flea Populations and Flea-Gender Analysis in Heavily Flea Infested Private Residences and Populations on Naturally Infested Pets in Tampa FL, 13 Years After Fipronil Introduction" is the report upon which that article is based.

Thank you for your time and efforts in evaluating this additional data. If I may be of any assistance in your review, please feel free to contact me at your convenience.

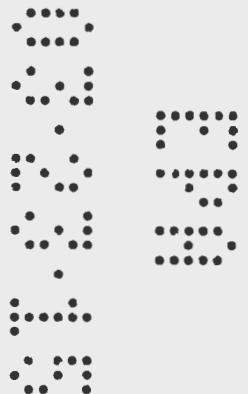
Sincerely,



David Jones
Manager Regulatory Affairs

Encl.

cc: S. McNear, L. Hemsarth



TRANSMITTAL DOCUMENT

Submitter:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Company Contact: David Jones

Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

Regulatory Action in Support of Which This Package is Submitted:

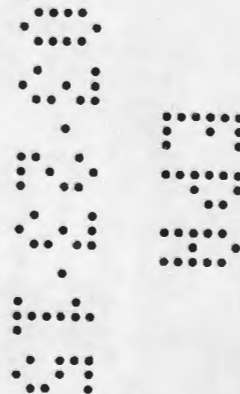
EPA Reg. No. 2596-179; HARTZ Reference #144 response to agency request for additional information regarding public literature citations

Submission Date:

03/18/2015

List of Submitted Documents:

Cover letter
Application Form (3 copies)
Certification with Respect to Data
Data Matrix
Data Matrix, confidential public copy
No Claim of Confidentiality Statement
Original report with raw data (3 copies)





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-179	2. EPA Product Manager K. Davis	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #144	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation, 400 Plaza Dr. Secaucus, NJ 07094 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Response to agency request to supply report including raw data for study cited from public literature.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Jones	Title Mgr. Regulatory Affairs	Telephone No. (Include Area Code) (201) 271-4800
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager Regulatory Affairs	
Typed Name David Jones	5. Date March 18, 2015	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corp., 400 Plaza Dr., Secaucus, NJ 07094; (201)271-4800	EPA Registration Number/File Symbol 2596-179
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-Methoprene, Pyriproxyfen	Date March 18, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential indoor	Product Name Hartz Reference #144

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION


I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date March 18, 2015	Typed or Printed Name and Title David Jones/Mgr. Regulatory Affairs
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
Washington, DC. 20460

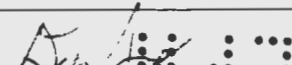
Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.2 hours per response for registration of activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 301 M. Street, S.W. Washington, DC 20460. Do not send the form to this address

DATA MATRIX

Date March 18, 2015	EPA Reg No./File Symbol 2596-179	Page 1 of 5
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #144	
Ingredients:		
Guideline Reference Number	Guideline Study Name	MRID Number
		Submitter
		Status
		Note

830.1550	Product Identity and Composition	49115602	Hartz	Own	
830.1600	Description of Materials Used to Produce the Product	49115602	Hartz	Own	
830.1620	Description of the Production Process	49115602	Hartz	Own	
830.1650	Description of the Formulation Process	49115602	Hartz	Own	
830.1670	Discussion of Formation of Impurities	49115602	Hartz	Own	
830.1700	Viscosity	49115601	Hartz	Own	
830.1750	Certified Limits	49115602	Hartz	Own	
830.1800	Enforcement Analytical Method	49115603	Hartz	Own	
830.6302	Color	49115601	Hartz		Self-certification
830.6303	Physical State	49115601	Hartz		Self-certification
830.6304	Odor	49115601	Hartz		Self-certification
830.6314	Oxidation/Reduction Chemical Incompatibility	49222901	Hartz	Own	

Signature 	Name and Title David Jones/ Mgr. Regulatory Affairs	Date March 18, 2015
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
Washington, DC 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.2 hours per response for registration of activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 301 M. Street, S.W. Washington, DC 20460. Do not send the form to this address

DATA MATRIX

Date March 18, 2015	EPA Reg No./File Symbol 2596-179	Page 2 of 5			
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #144				
Ingredients:					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

830.6315	Flammability	49115601	Hartz		Self-certification
830.6316	Explosibility	49222901	Hartz	Own	
830.6317	Storage Stability	To be submitted	Hartz		In progress
830.6319	Miscibility	49115602	Hartz	Own	
830.6320	Corrosion Characteristics	To be submitted	Hartz		In Progress
830.6321	Dielectric Breakdown Voltage	49222901	Hartz	Own	
830.7000	pH	49222901	Hartz	Own	
830.7300	Density/Relative Density/Bulk Density	49115601	Hartz	Own	
870.1100	Acute Oral Toxicity	44942004	Merial	Pay	
870.1200	Acute Dermal Toxicity	44942005	Merial	Pay	
870.1300	Acute Inhalation Toxicity	49222901	Hartz	Own	

Signature 	Name and Title David Jones/ Mgr. Regulatory Affairs	Date March 18, 2015
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
Washington, DC 20460

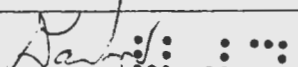
Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.2 hours per response for registration of activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 301 M. Street, S.W. Washington, DC 20460. Do not send the form to this address

DATA MATRIX

Date March 18, 2015	EPA Reg No./File Symbol 2596-179	Page 3 of 5			
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #144				
Ingredients:					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

870.2400	Acute Eye Irritation	44942006	Merial	Pay	
870.2400	Acute Eye Irritation	48405805	Hartz	Own	
870.2500	Acute Dermal Irritation	44942007	Merial	Pay	
870.2600	Skin Sensitization	44942008	Merial	Pay	
870.7200	Companion Animal Safety	44942009	Merial	Pay	
870.7200	Companion Animal Safety	49222901	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684601	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684602	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684603	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684604	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684605	Hartz	Own	

Signature 	Name and Title David Jones/ Mgr. Regulatory Affairs	Date March 18, 2015
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
Washington, DC, 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.2 hours per response for registration of activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 301 M. Street, S.W. Washington, DC 20460. Do not send the form to this address

DATA MATRIX

Date March 18, 2015	EPA Reg No./File Symbol 2596-179	Page 4 of 5			
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #144				
Ingredients:					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

40 CFR 157 Subpart B	Child Resistant Package Testing	48684606	Hartz	Own	
870.4100	Acute Toxicity, Chronic Toxicity	42178309	Sumitomo		FOR
810.3300	Treatments to Control Pests of Humans and Pets	43577716	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45618501	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628101	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628102	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628103	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628104	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	46019201	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	46019202	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	49115604	Hartz	Own	

Signature 	Name and Title David Jones/ Mgr. Regulatory Affairs	Date March 18, 2015
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. S.W.
Washington, DC 20460

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DATA MATRIX

Date March 18, 2015	EPA Reg No./File Symbol 2596-179	Page 5 of 5			
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #144				
Ingredients:					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

810.3300	Treatments to Control Pests of Humans and Pets	49455301	Hartz		Own / Public Lit
810.3300	Treatments to Control Pests of Humans and Pets	Submitted	Hartz		Per

↑
needs to
be deleted

31.03.20

Signature 	Name and Title David Jones/ Mgr. Regulatory Affairs	Date March 18, 2015
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Recommendation of Division Directors Negotiated Due Dates			
Decision #:494678		Registration #:2596-178	
494679		2596-179	
<input checked="" type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Fipronil, S-Methoprene, pyriproxyfen			
Fee Category: R340		PRIA Decision Time Frame: 4 mos	
Submitted by: Autumn		Metzger	Branch: OCSPP/OPP/RD Date: 01/20/2015
Company: The Hartz Mountain Corp.			
Original PRIA Due Date: 01/23/2015		Proposed New PRIA Due Date: 07/01/2015	
Previous Negotiated Due Dates:			
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 03/31/2015	
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input checked="" type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input checked="" type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input checked="" type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
see below for explanation			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
1/8/15-the product memo and 75 day deficiency letter was sent to co.			
1/16/15 - co. explained they could get the raw data for one of the field studies and submit to us, co request a 60 day PRIA ext. we say no			
1/20/15-co. requests PRIA extension of 90 days past guaranteed date of data giving PRIA date of 7-1-15			
"75 Day" Letter sent? <input checked="" type="checkbox"/> Yes, Date sent 01/08/2015 <input type="checkbox"/> No and reason for none? Add comments on page 2			
Rationale for Proposed Due Date: gives RD 90 days once we receive data.			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US			Date: 01/21/2015

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

- Company submitted citation of public literature to gain new efficacy claims: "kills pests in the 'home environment'"
- Efficacy review states that cited data was insufficient to support claims
- Memo and 75 day letter sent to co.
- Co. stated that they could get raw data for our efficacy team to review of "key" field study they think will be extensive and support claims and guarantees data to us by 3/31/15.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf

Form Number: PRIA

Document Identifier: PRIA-15020151028-AM

SUBMITTED on 01/20/2015 at 03:37:34 PM by CN=Autumn Metzger/OU=DC/O=USEPA/C=US

APPROVED on 01/20/2015 at 03:54:48 PM by CN=Marietta Echeverria/OU=DC/O=USEPA/C=US

APPROVED on 01/20/2015 at 04:59:45 PM by CN=Susan Lewis/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 01/21/2015 at 07:54:11 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

January 20, 2015

FedEx and Electronic

Office of Pesticide Programs
Registration Division (7505P)
Attn: A. Metzger/ PM Team 3
U.S. Environmental Protection Agency
One Potomac Yard, 2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Data Deficiency, EPA Reg. No. 2596-178, Decision No. 494678 and
EPA Reg. No. 2596-179, Decision No. 494679
Response to Letter dated January 9, 2015

Dear Ms. Metzger,

The Hartz Mountain Corporation (Hartz) is in receipt of the subject letter. After reviewing the letter and cited options we are requesting the establishment of a new PRIA due date. We are in the process of acquiring the data for one of the key field studies cited. We believe it is extensive. The tested material is essentially similar to the products at issue. With the acquisition not yet complete we propose the following timetable.

1. Additional data – By March 31, 2015 Hartz will submit the raw data and any all other relevant information obtained to the agency.
2. Extension of PRIA due date – We request the agency establish a new due date 90 days after the data is to be submitted, July 1, 2015.

We hope the agency finds this proposal acceptable. A discussion of the matter is welcomed should there be any questions or concerns.

Sincerely,

A handwritten signature in dark ink, appearing to read "David Jones", written in a cursive style.

David Jones
Manager of Regulatory Affairs
(201) 271-4800, ext. 7414
Encl. – Original letter
cc: S. McNear, L. Hemsarth



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

January 9, 2015

David Jones
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Subject: Data Deficiency
EPA Reg. No. 2596-178; Decision No. 494678
EPA Reg. No. 2596-179; Decision No. 494679
Application Date: 8/22/2014
EPA Receipt Date: 8/25/2014

Dear Mr. Jones:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **3/24/2015** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time.

1. The cited literature provides supplemental information on the ability of pet spot-on products to control/prevent fleas in the home environment. However, these citations do not stand alone. A GLP experiment must be conducted to show that this product performs as claimed. Therefore, the proposed claims listed below are not acceptable based on citation of literature:

- a. "Controls flea infestations on treated dogs/cats/etc. and prevent infestations in the home."
- b. "Prevents fleas on treated dogs/cats/etc. from infesting (re-infesting) your home."

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

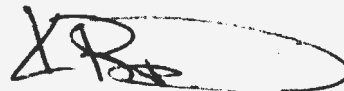
FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on 1/23/2015. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than 1/16/2015 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than 1/16/2015 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by 1/16/2015, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by 1/16/2015 by Autumn Metzger at 703-305-5314 or metzger.autumn@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, loopy oval shape.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

From: Kevin Sweeney, Senior Entomologist

A handwritten signature in black ink, appearing to read "Kevin Sweeney", with a checkmark at the end.

Date: January 8, 2015

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

This is a primary review.

DP barcodes: 423693 and 423696

Decision Nos.: 494678 and 494679

Submission Nos: 956753 and 956754

Action code: R340

Product Names: Hartz Reference #143 and #144

EPA Reg. Nos: 2596-178 and 2596-179

Formulation Type: pet spot-ons

Ingredients statement from the label with PC codes includes:

2596-178 = 9.8% fipronil, pc code 129121; 0.25% pyriproxyfen, pc code 129032; and 11.80% (S)-methoprene, pc code 105402.

2596-179 = 9.8% fipronil, pc code 129121; 0.25% pyriproxyfen, pc code 129032; and 11.80% (S)-methoprene, pc code 105402.

Application rate(s) of product: linear dose increments depending upon the weight range as directed by the label.

2596-178 = product dose range from lowest weight class is 0.67 ml (0.023 fl. oz.) (5 lbs) to 4.02 ml (0.136 fl. oz.) (132 lbs.) for the highest weight class.

2596-179 = 1.5 ml (0.051 fl. oz.) applied to cats weighing 3 lbs or more.

Use pattern:

2596-178 is a spot-on for dogs. Apply in a continuous band along the dorsal midline from head to tail.

2596-179 is a spot-on for cats. Apply in a single spot between the shoulder blades on the back of the cat.

OCSPP/OPPTS Guidelines: OPPTS 810.3300.

I. Action Requested: Review cited public literature in support of a label amendment. Registrant has requested that the following claims be added to the labels of both products:

“Controls flea infestations on treated cats (and kittens) (&kittens) and prevent infestations in the home.”

“Prevents fleas on treated cats (and kittens) (&kittens) from infesting (reinfesting) your home”

II. Background: The cited literature presents data on a variety of insecticide combinations applied as a spot on to pets. Hartz wishes to use these data to support the above claims, which indicate that applying their product to a pet will control /prevent flea infestations in the home/indoor premises. EPA and Hartz met on October 14, 2014 to discuss these claims and the data needed to support them. Hartz presented a discussion on a new study to EPA and EPA provided input on study design. Concurrently, Hartz advised EPA that the subject amendment was pending and included claims that will be tested in the proposed study. Instead of relying on the proposed study results, they requested EPA to review and rely only on cited published literature to support the claims. EPA advised Hartz that public literature does not stand-alone, but may be used as part of a weight of the evidence approach to supplement a study testing the label claims for control and prevention of fleas in the home.

III. Study Review:

No product specific data were submitted to review. Instead, the registrant submitted a list of public literature citations.

MRID49455301. Volume 1: Supplemental Information - White Paper. “Submission of Laboratory and Field Studies to Confirm Topical Parasiticide Applications Control Pre-Existing In-Home Flea Infestations and Specific Support of In-Home Infestation Control Claims for EPA Reg. Nos. 2596-178 and -179.”

The white paper included the following citations. I included the registrants’ explanations from their white paper.

“1. Jacobs, D. E., M. J. Hutchinson, D. Ewald-Hamm. 2000. Inhibition of immature *Ctenocephalides felis felis* (Siphonaptera: Pulicidae) development in the immediate environment of cats treated with imidacloprid. *Journal of Medical Entomology* 37 (2): 228-230.

Jacobs et al. (2000) showed that treated cats had transferred sufficient imidacloprid residues to blankets after a 6 hour contact per day, for 5 days. A new blanket was used each week for 4 weeks. Pre-adult flea viability on blankets was reduced by 100%, 84%, 60% and 74% in the 1st, 2nd, 3rd, and 4th week after treatment, respectively.

Entomologist’s Conclusion: Unacceptable. The product tested was not similar to the subject product.

2. Jacobs, D. E., M. J. Hutchinson, D. Stanneck. 2001. Accumulation and persistence of flea larvicidal activity in the immediate environment of cats treated with imidacloprid. *Medical and Veterinary Entomology* 15: 342-345.

In another study, Jacobs et al. (2001) used the same test design except for increasing the contact periods to 10 or 20 6-hour blanket contact periods over 2 and 4 weeks, respectively. Results showed that the degree of control was significantly higher after 26 days achieving pre-adult flea control of 100% and 97.4% after 10 or 20 days of blanket exposure, respectively.

Entomologist's Conclusion: Unacceptable. This study was conducted with an imidacloprid based formulation that was not similar to the subject product.

3. Ross, D. H., R. G. Arther, C. von Simson, V. Doyle, M. W. Dryden. 2012. Evaluation of the efficacy of topically administered imidacloprid + pyriproxyfen and orally administered spinosad against cat fleas (*Ctenocephalides felis*): Impact of treated dogs on flea life stages in a simulated home environment. *Parasites & Vectors* 5:192.

Ross et al. (2012) evaluated pre-adult flea control of an orally administered ectoparasiticide versus a topical imidacloprid/pyriproxyfen application. Dogs were housed in pens with floor mats that could be sampled for flea development. Flea infestations were established on-animal 1, 16 and 21 days prior to ectoparasiticide administration. Results showed topical application of the imidacloprid/pyriproxyfen formula resulted in transfer of active ingredients to floor matting. After only 1 week of exposure to treated dogs, floor mat samples provided better than 95% control of adult flea emergence.

While laboratory studies have shown the ability of treated pets to transfer effective amounts of active ingredient within simulated home environments, the same transfer of parasiticide active ingredients under in-home conditions has been demonstrated through field testing.

Entomologist's Conclusion: Unacceptable. This study was conducted with a formulation that contained spinosad.

4. Dryden, M. W., H. Perez, and D. Ulitchny. 1999. Control of fleas on pets and in homes by use of imidacloprid or lufenuron and a pyrethrin spray. *JAVMA* 215 (1):39-39.

Dryden et al. (1999) investigated existing household flea infestations. The ability for topical parasiticides and oral parasiticides to control in-home infestations was evaluated. It is critical to note that other flea treatments, either applied to the pets or their surrounds, were not used during the study. As well, no restrictions were made regarding exposure of pets to rain, swimming and outdoor activity. Results showed the incidence of fleas on pets and pre-adult flea populations living in the home were reduced by the topical parasiticide application containing imidacloprid. On-animal flea control was achieved within 1 week and in-home infestation was reduced by 86.8% after 4 weeks.

Entomologist's Conclusion: Unacceptable. The product tested was not similar to the subject product as it contained an IGR and adulticides not present in this formulation.

5. Dryden, M. W., J. M. Deneberg, S. Bunch. 2000. Control of fleas on naturally infested dogs and cats and in private residences with topical spot applications of fipronil or imidacloprid. *Vet Parasitol.* 93: 69-75.

In a follow up study, both fipronil and imidacloprid were evaluated for on-animal and infestation control potential. The same conditions existed for no other pesticide treatments being during the test as well as no restrictions on pets' activities or movement. Results showed on-animal control was achieved for both active ingredients after 1 week. In-home infestation control was as well achieved for both active ingredients exceeding 89.0% after 4 weeks. (Dryden et al. 2000).

Infestation control for both of these studies confirms transfer of active ingredients from treated the in-home environment to control pre-adult flea infestations.

Entomologist's Conclusion: Supplemental. One of the adulticides, fipronil, is present in the formulation at the same level but a complete data set was not provided. Furthermore, the author relied on visual hand counts for assessing flea infestation levels on the animal instead of comb counts.

6. Maynard, L. P. Houffschmitt, and B. Lebreux. 2001. Field efficacy of a 10 percent pyriproxyfen spot-on for the prevention of flea infestations on cats. Journal of Small Animal Practice 42: 491-494.

Maynard et al. (2001) evaluated an IGR only application and the effects it had on in-home flea infestations. Topical application of a 10% pyriproxyfen formula resulted in flea infestation control, measured by 'zero-flea' cats, increasing through the study from 49% control on day 30 to 88% control on day 180. In this study, no restrictions were placed on pets' activities including movement outdoors. It was concluded that appropriately timed topical applications of pyriproxyfen offer a method of flea control in the domestic environment.

Entomologist's Conclusion: Unacceptable. The formulation is not similar to the subject product and amount of pyriproxyfen applied to the cats is not equivalent to the dose to be delivered by the subject product.

7. Dryden, M. W., P. Payne, v. Smith, B. Riggs, J. Davenport, and D. Kobuszewski. 2011a. Efficacy of dinotefuran-pyriproxyfen-permethrin and fipronil-(S)-methoprene topical spot-on formulations to control flea populations in naturally infested pets and private residences in Tampa, FL. Vet. Parasitol. 182:281-286.

Dryden et al. (2011a) repeated an in-home field trial methodology to investigate a dinotefuran/pyriproxyfen/permethrin topical formula versus topically applied fipronil/(S)-methoprene. The fipronil/(S)-methoprene formula provided in-home pre-adult infestation control greater than 88% after 4 weeks. Greater than 96% was achieved after 6 and 8 weeks showing progressive in-home infestation control over time with monthly treatments.

Entomologist's Conclusion: Supplemental. The data from the dinotefuran-pyriproxyfen-permethrin formulation are not relevant to this amendment. The data from the fipronil-methoprene combination products provide supporting data that may be useful in a weight of the evidence approach as the concentration of fipronil and methoprene are similar to the subject product. However, these data cannot stand-alone as they are not complete data sets. The % control at 30 days is less than 90% (Study Table 1).

8. Dryden, M.W., D. Carithers, A. McBride, B. Riggs, L. Smith, J. Davenport, V. Smith, P. Payne, S. Gross. 2011b. A comparison of flea control measurement methods for tracking flea populations in highly infested private residences in Tampa FL, following topical treatment of pets with Frontline® Plus(Fipronil/(S)-Methoprene). Intern J. Appl. Res. Vet. Med. 9:356-367.

Dryden et al. (2011b) made an assessment of extremely high in-home flea populations with reinfestation pressure from outside environments. A fipronil/(S)-methoprene formula was tested. Significant flea populations existed in the homes studied. Heavy pressure from outdoor wild animal sources existed. With this constant pressure, over the 60 day study, the percent reduction in unfed adult flea emergence from Day 0 and from maximum trap counts in all homes studied were 85.4% and 92.5%, respectively. Under these excessive test conditions, reduction in flea egg production and the transfer of ectoparasiticide active ingredients in the home by treated pets provided significant infestation control.

Entomologist's Conclusion: Supplemental. The product tested a Merial product containing a similar level of methoprene and fipronil. The data were not collected with the subject product and

complete data sets are not available. This citation may be useful in a weight of the evidence approach to supplement a product specific study.

9. Dryden, M. W., P. Payne, V. Smith, M. Chwala, E. Jones, J. Davenport, G. Fadl, M. F. Martinez-Perez de Zeiders, K. Heaney, P. Ford, F. Sun. 2013. Evaluation of indoxacarb and fipronil (S)-methoprene topical spot-on formulations to control flea populations in naturally infested dogs and cats in private residences in Tampa FL. USA. *Parasites & Vectors* 6:366.

Dryden et al. (2013) also made comparison of formulas containing fipronil/(S)-methoprene versus indoxacarb. The study was done in naturally infested homes. Infestations were noted as the highest ever recorded in Tampa, Florida. Over 2 months, results showed the in-home pre-adult flea infestation control achieved for indoxacarb and fipronil/(S)-methoprene formulas were 97.7% and 84.6%, respectively.

Entomologist's Conclusion: Supplemental for reasons stated for the previous study.

Hartz Conclusions:

"All studies, both laboratory as well as field studies, document in-home pre-adult flea infestation control can be achieved by topical ectoparasiticide treatments. Specifically, laboratory testing under simulated home conditions have substantiated that effective residues of ectoparasiticide formulas do transfer from treated pets to surrounding surfaces. As seen from field trials, those residues in addition to the reduction in viable eggs being laid on-animal are sufficient to provide pre-adult flea infestation control in the home even under severe adult flea re-infestation pressure.

As for the three field trials discussed above evaluating fipronil/(S)-methoprene topical formulas, and cats were treated with fipronil (9.8% w/w)-(S)-methoprene (8.8% w/w) and fipronil (9.8% w/w) -(S)-methoprene (11.8% w/w), respectively. Results showed flea infestations in the home environment were reduced by over 88% in 4 weeks, by over 92% from peak population counts over 2 months and by over 84% in 2 months. Even with constant heavy pressure from the outside environment, monthly re-applications of a fipronil/(S)-methoprene formula, and no secondary environmental pesticide applications, in-home flea infestations that existed prior to test product application were controlled over a 1 to 2 month period (Dryden et al. 2011a, 2011b, 2013).

These 3 field studies are submitted specifically in support of the claims,

"Controls flea infestations on treated (insert pet) and prevent infestations in the home."

"Prevents fleas on treated (insert pet) from infesting (reinfesting) your home." for EPA registration 2596-178 and 2596-179."

Entomologist's Conclusion: The Dryden et al. studies provide supplemental evidence that transfer of S-methoprene and fipronil may take place in the home. Light trap data were used to survey for fleas but visual hand-counts on the animal were also used. These studies do not meet GLP requirements and were not conducted under an Experimental Use Permit.

IV. Entomologist's Recommendations:

1. The cited literature provides supplemental information on the ability of pet spot-on products to control/prevent fleas in the home environment. However, these citations do not stand alone. A GLP experiment must be conducted to show that this product performs as claimed. Therefore, the proposed claims are not acceptable based on citation of literature.

The last three studies by Dryden were the most relevant citations but this published literature did not provide the raw data or meet the requirements of GLP. Furthermore, the studies were not

conducted with the subject product or with a product that is substantially similar to the subject product.

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 8-25-14 September 2012

Experts In-Processing Signature: BB Date 8-27-14 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2596-179</u>		EPA Receipt Date: <u>8-25-14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)					X
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>*no inerts to review</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X	
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

- Contacted the submitter via email on 9/2/14 for corrections to studies and application
- received corrections on 9/5/14 via email
- Submitted studies PASSED PRN 11-3 Review
- no inerts to review, no CSF submitted w/ application
- Jacket PASSED

RE

MRID: 494553

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Cipicchio, Carleigh

From: Cipicchio, Carleigh
Sent: Friday, September 05, 2014 4:07 PM
To: 'DJones@hartz.com'
Cc: Ashe, Anthony; Correa, Leah
Subject: RE: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

Dave,

Thank you for sending the corrections. I will send both applications up to the appropriate product manager for further review.

Have a great weekend,

Carleigh

Carleigh Cipicchio
EPA Contractor
2777 S. Crystal Dr, S-4813
Arlington, VA 22202
ph: (703)347-0240
cipicchio.carleigh@epa.gov

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Friday, September 05, 2014 11:52 AM
To: Cipicchio, Carleigh
Cc: Ashe, Anthony; Correa, Leah
Subject: RE: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

Hi Carleigh,
I have attached the three documents requested below. Please let me know if I can provide any further support to the submissions.
Enjoy your weekend!
Thank you,
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Cipicchio, Carleigh" <Cipicchio.Carleigh@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>, "Correa, Leah" <Correa.Leah@epa.gov>
Date: 09/04/2014 10:56 AM
Subject: RE: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

Dave,

A Certification with Respect to Data is still required because you submitted supporting material. Since these are new submissions, a new certification will need to be generated for each product (EPA Reg #'s 2596-178 and 2596-179).

Again, please do not hesitate to contact me if you have any more questions.

Best Regards,

Carleigh

Carleigh Cipicchio
EPA Contractor
2777 S. Crystal Dr, S-4813
Arlington, VA 22202
ph: (703)347-0240
cipicchio.carleigh@epa.gov

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Thursday, September 04, 2014 9:38 AM
To: Cipicchio, Carleigh
Cc: Ashe, Anthony; Correa, Leah
Subject: Re: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

Good morning Carleigh,
Thank you for the e-mail. I had not submitted a "Certification with Respect to Data" as we only summarized a set of public literature articles. Will the certification be required? If so, will a copy of the original certification filed with the initial application meet the requirement or should I generate another?
I will sign and resend the data confidentiality page.
Again thank you for the guidance.
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Cipicchio, Carleigh" <Cipicchio.Carleigh@epa.gov>
To: "djones@hartz.com" <djones@hartz.com>,
Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>, "Correa, Leah" <Correa.Leah@epa.gov>
Date: 09/02/2014 04:02 PM
Subject: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

Mr. Jones,

This email is to address an issue that was found regarding your applications for submission of the products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179).

In regards to product Hartz Reference #143 (EPA Reg #2596-178):

- A Certification with Respect to Citation of Data is required because you submitted studies with the application.

In regards to product Hartz Reference #144 (EPA Reg #2596-179):

- A Certification with Respect to Citation of Data is required because you submitted studies with the application.
- There was a deficiency with Volume 1 of the studies submitted:
 - MRID 49455301: You failed to sign the statement of data confidentiality claims included in the study (page 2). Please sign and resend.

Please email these corrections to me by Friday September 6. If you have any questions or concerns, please do not hesitate to contact me.

Best Regards,

Carleigh

Carleigh Cipicchio
EPA Contractor
2777 S. Crystal Dr, S-4813
Arlington, VA 22202
ph: (703)347-0240
cipicchio.carleigh@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 26, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-494679
EPA File Symbol or Registration Number: 2596-179
Product Name: HARTZ REFERENCE # 144
EPA Receipt Date: 25-Aug-2014
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORPORATION

DAVID JONES
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "mjk", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

W
{956754F~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S- 956754

EPA File Symbol/Reg. No.

2596-179

Pin-Punch Date:

8/25/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R340

Granted: R340

Amount Due: \$ 3,198

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *Jennifer Gaines*

Date: 8/26/14

Remarks:

S: 956754

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Bilable: ☒ Yes ☐ No

Print Letter

Enter More Information

Tracking

Company: 2596 THE HARTZ MOUNTAIN CORPORATION



Risk Manager: Registration Division, Risk Management Team 10

Product #: 2596-179

Product Name: HARTZ REFERENCE # 144

Override:

Me Too

Section3: Me Too Product

Section3:

Name:

Application Date: 22-Aug-2014



OPP Rec'd Date: 25-Aug-2014



Front End Date: 25-Aug-2014



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT/STUDIES

Receipt Content

Study

Paper Label

View/Edit

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



49455300

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

August 22, 2014

FedEx Delivery

Document Processing Desk (Distribution Code-REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Label amendment application, Hartz Reference #144, EPA Reg. No. 2596-179
Note: Identical data (white paper) submitted concurrently for EPA Reg. No. 2596-178

Dear Sir/Madam,

Enclosed please find a pesticide registration amendment package for Hartz Reference #144. This package supports these actions:

1. Label changes
 - a. Add 2 lines claiming for home environment control of fleas (on next to last page)
 - b. Expanded the list of additional brand names (ABNs) to remove parentheses
 - c. Removed the claim "Made in USA"
 - d. Inserted the EPA Registration number assigned.
2. Additional efficacy claim - A white paper summarizing various public literature articles (public literature, copies enclosed) is tendered in support of two additional home environment efficacy claims. These statements are similar to language existing on similar products on the market today.
3. Data matrix update
 - a. Includes new MRIDs assigned since the last matrix filing
 - b. Inserted a new line at the bottom of the first page for the white paper enclosed

Enclosed is check no. 33358 payable to the US Environmental Protection Agency in the amount of \$3738 for our PRIA Code R340 submission. The same white paper is being submitted concurrently for EPA Reg. No.s 2596-178 and 2596-179.

Please call if I can answer any questions or address any concerns.

Sincerely,

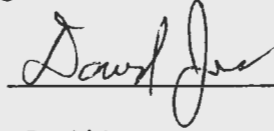
David Jones
Manager Regulatory Affairs
(201) 271-4800, ext. 7414

TRANSMITTAL DOCUMENT

Submitter:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Company Contact:



Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

Regulatory Action in Support of Which This Package is Submitted:

EPA Reg. No. 2596-179; HARTZ Reference #144; PRIA Code R340

Amendment actions:

- Add efficacy claims (2) based on a white paper supported by several public literature articles (copies included).
- Updating data matrix to incorporate MRIDs assigned for granted data waiver requests and reference white paper submission.
- Deleting claim "Made in USA"
- Expanding ABNs to eliminate parenthetical options in alternate product names

Submission Date:

08/22/2014

List of Submitted Documents:

Cover letter

Amendment Form

Data Matrix

Data Matrix, confidential public copy

TRANSMITTAL DOCUMENT (cont.)

Proposed Label Text (Five copies)

Proposed Label Text (One highlight version of prior stamped label)

PRIA Fee, Check No. 33358 for \$3798.00

MRID#

Volume 1 **49455301**

Transmittal document

Cover letter (copy)

Title Page

No Data Confidentiality Statement

White Paper

Referenced articles for white paper



United States
Environmental Protection Agency
Washington, DC 20460

☐
☒
☐

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-179	2. EPA Product Manager R. Gebken	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #144	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation, 400 Plaza Dr. Secaucus, NJ 07094 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment adding efficacy claims (2) based on a white paper based on specific public literature articles.
Updating data matrix to incorporate MRIDs assigned for granted data waiver requests and reference white paper submission.
Deleting claim "Made in USA", Adding EPA Reg. Number
Expanding ABNs to eliminate use of parentheses in names

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Jones	Title Mgr. Regulatory Affairs	Telephone No. (Include Area Code) (201) 271-4800
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager Regulatory Affairs	
4. Typed Name David Jones	5. Date August 22, 2014	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corp., 400 Plaza Dr., Secaucus, NJ 07094; (201)271-4800	EPA Registration Number/File Symbol 2596-179
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-Methoprene, Pyriproxyfen	Date Sept. 5, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential indoor	Product Name Hartz Reference #144

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Sept. 5, 2014

Typed or Printed Name and Title

David Jones/Mgr. Regulatory Affairs



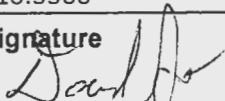
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date August 22, 2014	EPA Reg. No./File Symbol 2596-179	Page 1 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688	Product Hartz Reference #144	

Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Treatments to Control Pests of Humans and Pets	43577716	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45618501	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628101	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628102	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628103	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628104	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	46019201	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	46019202	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	49115604	Hartz	Own	
830.1550	Product Identity and Composition	49115602	Hartz	Own	
810.3300	Treatments to Control Pests of Humans and Pets	Submitted	Hartz	Own/ Public Lit	
Signature 			Name and Title David Jones Manager Regulatory Affairs		Date Aug. 22, 2014




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	August 22, 2014	EPA Reg. No./File Symbol	2596-179	Page 2 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1600	Description of Materials Used to Produce the Product	49115602	Hartz	Own	
830.1620	Description of the Production Process	49115602	Hartz	Own	
830.1650	Description of the Formulation Process	49115602	Hartz	Own	
830.1670	Discussion of Formation of Impurities	49115602	Hartz	Own	
830.1700	Viscosity	49115601	Hartz	Own	
830.1750	Certified Limits	49115602	Hartz	Own	
830.1800	Enforcement Analytical Method	49115603	Hartz	Own	
830.6302	Color	49115601	Hartz	Self-certification	
830.6303	Physical State	49115601	Hartz	Self-certification	
830.6304	Odor	49115601	Hartz	Self-certification	
Signature 		Name and Title David Jones Manager Regulatory Affairs		Date Aug. 22, 2014	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

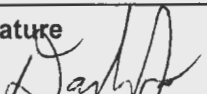
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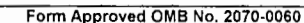
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DATA MATRIX

Date August 22, 2014	EPA Reg. No./File Symbol 2596-179	Page 3 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688	Product Hartz Reference #144	

Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/Reduction Chemical Incompatibility	49222901	Hartz	Own	
830.6315	Flammability	49115601	Hartz	Self-certification	
830.6316	Explosibility	49222901	Hartz	Own	
830.6317	Storage Stability	To be submitted	Hartz	In progress	
830.6319	Miscibility	49115602	Hartz	Own	
830.6320	Corrosion Characteristics	To be submitted	Hartz	In progress	
830.6321	Dielectric Breakdown Voltage	49222901	Hartz	Own	
830.7000	pH	49222901	Hartz	Own	
830.7300	Density/Relative Density/Bulk Density	49115601	Hartz	Own	
870.1100	Acute Oral Toxicity	44942004	Merial	Pay	
Signature 			Name and Title David Jones Manager Regulatory Affairs	Date Aug. 22, 2014	



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DATA MATRIX

Date August 22, 2014

EPA Reg. No./File Symbol 2596-179

Page 4 of 5

Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation,
400 Plaza Dr., Secaucus, NJ 07094-3688

Product
Hartz Reference #144

Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Toxicity	44942005	Merial	Pay	
870.1300	Acute Inhalation Toxicity	49222901	Hartz	Own	
870.2400	Acute Eye Irritation	44942006	Merial	Pay	
870.2400	Acute Eye Irritation	48405805	Hartz	Own	
870.2500	Acute Dermal Irritation	44942007	Merial	Pay	
870.2600	Skin Sensitization	44942008	Merial	Pay	
870.7200	Companion Animal Safety	44942009	Merial	Pay	
	See next page				
Signature			Name and Title David Jones Manager Regulatory Affairs		Date Aug. 22, 2014



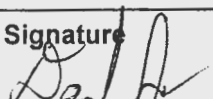

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DATA MATRIX

Date August 22, 2014	EPA Reg. No./File Symbol 2596-179	Page 5 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688	Product Hartz Reference #144	

Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Companion Animal Safety	49222901	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684601	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684602	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684603	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684604	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684605	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684606	Hartz	Own	
870.4100	Acute Toxicity, Chronic toxicity	42178309	Sumitomo	FOR	
Signature 			Name and Title David Jones Manager Regulatory Affairs	Date Aug. 22, 2014	64

Material Sent for Data Extraction

Reg. # 2596-179

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 4-4-14

☐ Notification Dated _____

☒ New CSF(s) Dated 3-11-14

☐ Other: _____

☒ Decision #: 483629


☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Carmen Rodia

Phone: (703) 306-0327 Division: RD/IB

Date: 4-4-14

	ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001	EPA Registration No. 2596-179	Date of Issuance: APR 4 2014
NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration (under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)		Term of Issuance: Conditional Name of Pesticide Product: Hartz® Reference #144	
Name and Address of Registrant (include ZIP Code): The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-368			
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This action is taken under the authority of section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p> <p style="text-align: center;">Terms of Registration</p> <ol style="list-style-type: none"> EPA has registered the product listed above provided that the following changes are made to the label before you release the product for shipment: <ol style="list-style-type: none"> Revise the EPA Registration Number to read: "EPA Registration No 2596-179" This registration is time-limited and expires two years (2) from the date this product is first released for shipment (April 4, 2016). You must provide the Agency with a projected "release for shipment date," in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient). Within twelve (12) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability). 			
Signature of Approving Official: Refer to Page #3 Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch		Date: APR 4 2014	

5. You must submit the following data within the timeframe described below:
Within twelve (12) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
6. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2014. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (attn: Kaitlin Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

- EPA Registration Number
 - Product name (brand name)
 - Lot#
 - Where purchased: internet, store, Veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred, (mm/dd/yyyy)
 - State in which the incident occurred, (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
7. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for
 - d. Summary table for cats and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. A summary table for s showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label.
 - g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range.
 - h. Table showing number of incidents for each cat breed.
 - i. Table showing number of incidents in cat for each clinical sign.
 - j. Table showing number of incidents in cat for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.

8. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
9. The Hartz Mountain Company must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site:
<http://www.epa.gov/pesticides/health/spot-on-meetings.html>.
10. Enclosed is a copy of the data call-in (DCI) for fipronil.

You must submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records along with hard copies of the similarity clinic memo as well as the child-resistant packaging, companion animal safety data, efficacy, product chemistry reviews completed in support of the registration of this new product. If you have any questions concerning this letter, please contact Ms. Carlyn Petrella at (703) 347-0439 or via e-mail at Petrella.Carlyn@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted with Comments," dated April 4, 2014*
Child-Resistant Packaging Review, dated March 10, 2014
Efficacy Review, dated March 18, 2014
Product Chemistry Review, dated March 7, 2014
Similarity Clinic Memo, dated December 11, 2013
Copy of DCI for Fipronil

002596-00179 D483629

April 3, 2014

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	78.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 weeks and older, weighing 3 lbs. or more.

ACCEPTED
With COMMENTS
In EPA Letter Dated:
April 4, 2014
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
2596-179

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS

April 3, 2014

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

April 3, 2014

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

April 3, 2014

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) that live in your home

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) to prevent the eggs from hatching in your home

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.
Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) prevents re-infestation

Contains two ingredients to prevent flea infestations

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

April 3, 2014

(With) patented applicator
(With) patent pending applicator
Waterproof
Effective after bathing
Effective after exposure to water
Patents Pending
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Fast-acting
- Long-lasting
- Waterproof

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more
Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose
First month, second month, third month
Value pack
3 month supply
3 monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
With Pro-cision Flo® Applicator
Featuring Pro-cision Flo® Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

April 3, 2014

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your cat 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____
Second Dose _____
Third Dose _____

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Nylar® - Registered Trademark of McGlaughlin Gormley King Company

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1



Decision Information for 2596-RTO

Decision Seq: 483629

Action Code: **R315,NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUB** ...

FFS Start Date: 22-Oct-2013

Tentative Ind: No

FQPA Clock:

Due Date: 22-Jul-2014

75-Day Due Date:

Days Elapsed:

OPP Target Due Date:

21-Day Due Date: 22-Oct-2013

FFS Original Decision: ...

Negotiated Due Date:

90-Day Due Date: 21-Jan-2014

Registrant



Predecisional

Due Date: 08-Jul-2014

Add to Bundle? ☐

Response Due Date:

Due Date:

Current Status: PENDING (04-Apr-2014)

Bundle ID:

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

Decision Bundle

Receipts	Staff Member	Reg/DC Number	Submission Due Date	Response
S:940100	Petrella, Carlyn	... 2596-RTO	22-Jul-2014	PENDING
Submission of FINAL updated master label.				
S:949988	Petrella, Carlyn	... 2596-RTO	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
Submission of further updated master label.				
S:949403	Petrella, Carlyn	... 2596-RTO	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
Submission of updated master label.				
S:941691	Petrella, Carlyn	... 2596-RTO	22-Jul-2014	SUPERSEDED BY NEW RECEIPT

Viewing Record 1 of 1

Rodia, Carmen

From: DJones@hartz.com
Sent: Thursday, April 03, 2014 5:11 PM
To: Rodia, Carmen
Cc: SMcNear@hartz.com; Petrella, Carlyn
Subject: EPA File Symbol 2596-RTO; Hartz Ref. #144
Attachments: tick Larvae Clemson.pdf; Tick Larvae Cornell.pdf; 065331-00004-20130828 p 3 of 20 tick stages.pdf; Master label Ref 144 EPA 2596-RTO Apr 3 2014.pdf

Carmen,

I appreciate your taking the time to discuss this label and comments. As mentioned, all comments are adopted except for this one we had agreed could be kept with supporting documentation:

Tick Larvae claim (p. 6 of 9) - As indicated, our entomologist had asserted that the tick life cycle does include a larval stage. In support he sent these two items, one tied to a link from the agency's website.

The Clemson article begins to talk about the tick larvae in the second paragraph. The Cornell article begins on page 2 under Biology and Behavior. We offer this to document the tick has a larval stage in its life cycle. The label attached for EPA Reg. No. 65331-4 upon which our data is cited shows tick larvae efficacy accepted by the agency on page 3 of 20.

The modified master label proposed is below. Again thank you for your time and efforts.

Sincerely,
Dave

April 3, 2014

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	78.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 weeks and older, weighing 3 lbs. or more.

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

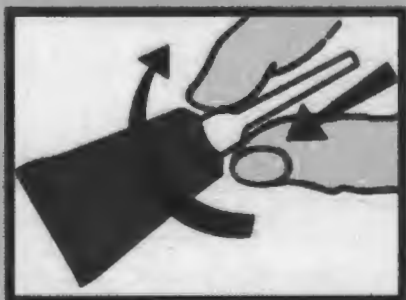
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS

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To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

April 3, 2014

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats
8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) that live in your home

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) to prevent the eggs from hatching in your home

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks
(for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

April 3, 2014

Prevents development of all flea stages for up to 3 months.
Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) prevents re-infestation

Contains two ingredients to prevent flea infestations

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator
(With) patent pending applicator
Waterproof
Effective after bathing
Effective after exposure to water
Patents Pending
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Fast-acting
- Long-lasting
- Waterproof

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more
Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose
First month, second month, third month
Value pack
3 month supply
3 monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
With Pro-cision Flo® Applicator
Featuring Pro-cision Flo® Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

April 3, 2014

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

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Nylar® - Registered Trademark of McGlaughlin Gormley King Company

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

Providing Leadership in Environmental Entomology

Department of Entomology, Soils, and Plant Sciences • 114 Long Hall • Clemson, SC 29634-0315 • Phone: 864-656-3111
email: dpento@clemson.edu

TICKS AROUND YOUR HOME

Ticks are closely related to scorpions, spiders and mites. They are not insects. They are external parasites that need a blood meal to survive and reproduce. Ticks can feed on humans and other mammals, reptiles, birds or even frogs. All life stages of ticks feed on blood. Ticks can transmit several diseases, such as Lyme disease, rocky mountain spotted fever, tick paralysis, and others, but most tick bites do not result in illness.

Life Cycle. Ticks have a simple life cycle. Eggs hatch into six-legged larvae, an immature stage. Depending on the kind of tick, the larva can be extremely active or lay in wait for a host to come. Once on the host, the larva will begin feeding. After the tick is full of blood, it will either fall off the host or stay on, depending on the type of tick. The next step for the tick is to turn into a nymph. From this point on, the tick will have eight legs. Some ticks go through many nymphal stages, while some only have one. The nymph will have a blood meal at every stage. After the nymph goes through all of its stages, it will turn into an adult. The adult will either stay on the original host, or find a new one if the nymph dropped off after feeding.

Types of Ticks. There are about 80 different kinds of ticks in the United States. Most of them are not associated with humans or their pets. The information presented here will help you understand what to do if you encounter one of the wood ticks or the brown dog tick in or around your home.



Deer Tick

Photo Source: Iowa State Univ.

Wood ticks. The name wood tick is used for many ticks including the blacklegged or deer tick, lone star tick and American dog tick. These are usually found in woodland areas. If a home is built in an

area that was recently a field or forest, there is a higher chance that these ticks will be close-by. They crawl around for several hours often before attaching themselves to a host, so they may be accidentally brought into a home on pets or clothing. Wood ticks do not establish populations indoors.

Brown dog tick. The brown dog tick can be a nuisance in the home. It is one of only a few ticks that will infest a structure. The brown dog tick prefers to feed on dogs, but will occasionally feed on other hosts, such as humans.



Brown Dog Tick

They usually are found only where dogs occur. They can be picked up in such common places as infested homes, kennels, veterinarian's office, or outdoor areas frequented by an infested animal. On the animal, the larval and nymphal stages of the tick are normally found in the long hair along the back of a dog. The adult stage is found in the ear or between the toes. When an infestation occurs indoors, ticks will be found in cracks, crevices, behind baseboards and in other protected places close to the floor. Since the brown dog tick and adult female can lay as many as 5,000 eggs, the infestation can be very large.

Prevention is the Key to Control. The best way to avoid tick bites and the diseases they may carry is to avoid ticks. The best way to do that is to avoid places where ticks live, such as wooded areas. That is not always possible, but precautions can be taken. Long-sleeved shirts, long pants and hats should be worn when in tick-infested areas. Ticks are easier to detect when you wear light-colored clothes. To prevent ticks from getting under plants, you should tuck cuffs into the

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Public Service Activities

socks or shoes. Tuck long hair under a hat. Also, tick repellent can be applied to the outside of clothes, especially the pants.

Do visual inspection of your clothes and body twice a day when in tick-infested areas. The larvae and nymphs of ticks are quite small and can be easily mistaken for freckles or dirt. Ticks like to feed on the back of the head at the base of the skull. It is a good idea to have another person check for ticks in places you cannot easily see. All clothing should be washed in warm water and detergent. If your pets accompany you to the woods, check them too.

Non-chemical Control. If you are having problems with rodents or other wild animals, such as raccoons or opossums, take measures to exclude them from your house or yard. Also, keep shrubs trimmed along the paths near your home. Keep grass mowed, and remove weeds, brush and leaf litter close to your house to reduce tick problems.

Chemical Control. Indoor chemical control of ticks is usually not recommended except for brown dog tick. Other ticks will not establish inside. In the case of the brown dog tick, applications should be limited to crack and crevice treatments, and areas where the animal spends the most time. Animal bedding or sleeping areas should receive special attention. Brown dog ticks will not be found in high places. Think about the brown dog tick as being at the level of the dog. You can use many of the same spray or dust products you would use for cockroach control to control brown dog ticks. Check the label for product that can be used in the same sites as those you need to treat. Always read and follow label instructions. At the same time that the home is treated for brown dog tick, also treat the animal with an approved product.

Outdoor treatments for any type of tick should be limited to those areas where pets spend the most time. Crawlspace, outdoor walls, cracks and crevices should only be treated if ticks are observed in these places. General treatments for ticks are not

recommended because they often are not very effective. Removal of tick habitats is much more helpful.

If you have a severe infestation in or around your home you may want to hire a professional pest control company to control your tick problem. Professionals can safely use products that are not available to consumers.

Tick Bites. As mentioned earlier, some ticks may transmit diseases. If a tick bites you, there are a few things that you should do. First, carefully remove the tick by grasping it with a pair of tweezers at the point closest to the skin. Pull it out slowly and steadily. After the tick is removed, disinfect the bite area. Also, make sure that you don't crush the tick because if the tick is infected, crushing it could introduce the disease into your body. Save the tick by placing it in a small container with rubbing alcohol. This way if you suspect a tick-related problem later on, the tick can be identified. Although, keep in mind, that to test the tick for disease, it must be kept alive. Finally, record the date on your calendar that you were bitten just in case symptoms appear later.

For other publications in our Entomology Insect Information Series visit our web site at <http://www.clemson.edu/esps>.

Prepared by Jonathan M. Sargent, Graduate Extension Assistant, Patricia Zungoli, Extension Entomologist/Professor, and Eric P. Benson, Extension Entomologist/Associate Professor, Department of Entomology, Soils, and Plant Sciences, Clemson University.

This information is supplied with the understanding that no discrimination is intended and no endorsement by the Clemson University Cooperative Extension Service is implied. Brand names of pesticides are given as a convenience and are neither an endorsement nor guarantee of the product nor a suggestion that similar products are not effective. Use pesticides only according to the directions on the label. Follow all directions, precautions and restrictions that are listed.
EHS/MV-5 (New 10/1998).

Rodia, Carmen

From: Rodia, Carmen
Sent: Wednesday, April 02, 2014 4:24 PM
To: DJones@hartz.com
Cc: McCall, Deborah; Gebken, Richard; Petrella, Carlyn
Subject: FINAL Label Review Comments for EPA File Symbol 2596-RTO (Hartz Reference #144)
Attachments: 2596-179 (Hartz Reference #144), E-Copy of Marked Up Label (04-02-14).pdf

David, in a FINAL attempt to obtain from The Hartz Mountain Company a "clean label" with no comments that can be used to out-process the STILL pending/EXPEDITED R315 new product registration for EPA File Symbol 2596-RTO (Hartz Reference #144), I have attached a FINAL "marked up" copy of the updated master label as well as a list of what we are calling our FINAL label review comments. This FINAL list of label review comments included changes necessary as part of the Agency's PERC committee meeting on April 1, 2014. As such, my FINAL label review comments are as follows:

OPTIONAL/ALTERNATE LABEL TEXT section comment(s), page 6-8 of 9:

1. You must delete all text within this section that has been marked with "~~strikethrough~~."
2. Within the "[Tick]" subsection in the middle of page 6 of 9, you must delete the word "larvae" since the tick life cycle does not include a larval life stage.

As such, you must submit a further amended master label which incorporates all of the remaining FINAL label review comments. If you have any questions, please call me directly. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

April 2, 2014

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
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FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	<u>78.15%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 weeks and older, weighing 3 lbs. or more.

April 2, 2014

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS**

April 2, 2014

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

April 2, 2014

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

~~Prevents establishment of flea infestation in the home~~

~~Prevents establishment of flea infestation in the home~~

~~Prevents establishment of flea infestation in the home~~

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (cat or kitten or cat and kitten) that live in your home

Kills flea eggs on your (cat or kitten or cat and kitten) to prevent the eggs from hatching in your home

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs ~~and larvae~~ Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

[illegible]

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Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

~~Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)~~

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

~~Each month, apply the product (IGP) to the dog's fur to prevent re-infestation in the home~~

[illegible]

SECRET

[illegible]

April 2, 2014

Dual insect growth regulator (IGR) ~~prevents re-infestation~~

Contains two ~~ingredients to prevent flea infestations~~

~~Contains two unique ingredients to prevent flea infestations in the home~~

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Effective after bathing

Effective after exposure to water

Patents Pending

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Fast-acting
- Long-lasting
- Waterproof

* Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more

* Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

[REDACTED]

April 2, 2014

Apply monthly (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your cat 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____
Second Dose _____
Third Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Nylar® - Registered Trademark of McGlaughlin Gormley King Company

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Decision Seq: 483629 Action Code: R315,NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUB

FFS Start Date: 22-Oct-2013 Tentative Ind: No Start/Stop Clock FQPA Clock:

Due Date: 22-Jul-2014 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: 22-Oct-2013 FFS Original Decision:

Negotiated Due Date: 90-Day Due Date: 21-Jan-2014

Registrant Predecisional Due Date: 08-Jul-2014 Add to Bundle? ☐

Response Due Date:

Current Status: PENDING (02-Apr-2014) Bundle ID:

- Decision Status
- Tracking
- Create Resubmission
- FFS Letters
- Waiver Documentation
- Action Code History
- Secondary Decision
- Decision Bundle

75 Day Letters

45/90 Day Screen

Primary Decisions

Decision Milestone

FFS Negotiated Due Dates

OPP Target Due Date

Decision Comments

Payment

Unmatched Payments

Decision Ownership

Receipts

Data Package

Reduced Risk

Meetings & Milestones

FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:949988	Petrella, Carlyn	2596-RTO	22-Jul-2014	PENDING
Submission of further updated master label.				
S:949403	Petrella, Carlyn	2596-RTO	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
Submission of updated master label.				
S:941691	Petrella, Carlyn	2596-RTO	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
INITIAL APPLICATION.				

Rodia, Carmen

From: DJones@hartz.com
Sent: Wednesday, April 02, 2014 12:25 PM
To: Rodia, Carmen
Cc: Petrella, Carlyn
Subject: EPA File Symbol. 2596-RTO: Master label Ref 144 EPA 2596-RTO Apr 2 2014.pdf, Master label Ref 144 EPA 2596-RTO Apr 2 2014 strikeout version.doc
Attachments: Master label Ref 144 EPA 2596-RTO Apr 2 2014.pdf; Master label Ref 144 EPA 2596-RTO Apr 2 2014 strikeout version.doc

Carmen,
Per the prior e-mail, attached is a highlight strikeout Word label and its corresponding pdf with edits implemented.
Again thank you for all your efforts.
Regards,
Dave

Master label Ref 144 EPA 2596-RTO Apr 2 2014.pdf
Master label Ref 144 EPA 2596-RTO Apr 2 2014 strikeout version.doc

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

Hartz® Reference #144
EPA Reg. No.: 2596-
MASTER LABEL- -

March 22 April 2, 2014

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
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First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	78.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 weeks and older, weighing 3 lbs. or more.

~~March 22~~ April 2, 2014

BACK PANEL

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

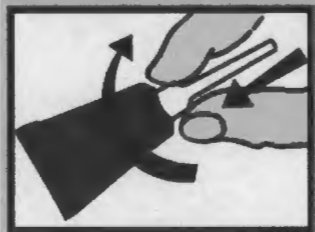
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS.
DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS

March 22 April 2, 2014

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Hartz® Reference #144
EPA Reg. No.: 2596-
MASTER LABEL- -

March 22 April 2, 2014

INDIVIDUAL TUBE TEXT

(Product Name)
Only for use on cats 8 weeks and older weighing 3 lbs or more
0.017 fl oz (0.5ml)
Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations
Kills adult fleas, flea eggs, and flea larvae
Prevents all flea stages (eggs, larvae, pupae) from developing
Kills fleas which may cause flea allergy dermatitis
Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks
Kills mosquitoes
Prevents and controls reinfestations
Rapidly eliminates infestations with chewing lice
Fast-acting
Long-lasting
Waterproof
Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)
Kills (Adult) Fleas (~~for up to 3 months~~)
Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~)
Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~)
Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~)
Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~) on cats 8 weeks or older weighing 3 lbs or more

Optional/alternate text in parentheses or brackets

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Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~) on cats 8 weeks or older weighing 3 lbs or more
Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs
If there is a high risk for flea reinfestation, a once a month application may be needed
Stops existing infestations
Prevents establishment of new infestations after application
Prevents establishment of new infestations after application in the home environment
~~Prevents establishment of new infestations after application on premises~~
Prevents establishment of new infestations in the home environment
~~Prevents establishment of new infestations on premises~~

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)
Prevents Flea Eggs from hatching
Kills flea eggs on your (cat or kitten or cat and kitten) that live in your home
Kills flea eggs on your (cat or kitten or cat and kitten) to prevent the eggs from hatching in your home

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[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)
Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice
Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

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Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.
Kills ~~adult Fleas~~, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Prevents flea eggs from developing into biting adults in the home ~~environment~~ (for) (up to) (30 days) (1 month) (4 weeks)
Prevents flea eggs from developing into biting adults ~~(on premises)~~ (for) (up to) (30 days) (1 month) (4 weeks)

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Stays on and doesn't rub off
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Dual insect growth regulator (IGR) technology prevents re-infestation in the home environment
Dual insect growth regulator (IGR) technology prevents re-infestation
~~Dual insect growth regulator (IGR) technology prevents re-infestation on premises~~
Contains two unique ingredients to prevent flea infestations
Contains two unique ingredients to prevent flea infestations in the home environment
~~Contains two unique ingredients to prevent flea infestations on premises~~
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Effective after bathing
Effective after exposure to water
Patents Pending
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Fast-acting
- Long-lasting
- Waterproof

~~Kill(s) Repel(s) Prevent(s)~~

~~New (Formula) (claim to be removed 6 months after date product is first sold or distributed)~~

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more

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Hartz® Reference #144
EPA Reg. No.: 2596-
MASTER LABEL- -

~~March 22~~ April 2, 2014

Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Nylar® - Registered Trademark of McGlaughlin Gormley King Company

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

April 2, 2014

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	<u>78.15%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 weeks and older, weighing 3 lbs. or more.

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

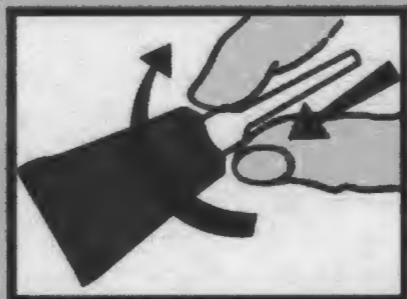
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS**

April 2, 2014

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

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Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

Prevents establishment of new infestations after application in the home

Prevents establishment of new infestations in the home

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) that live in your home

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) to prevent the eggs from hatching in your home

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

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Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation in the home

April 2, 2014

Dual insect growth regulator (IGR) technology prevents re-infestation
Contains two unique ingredients to prevent flea infestations
Contains two unique ingredients to prevent flea infestations in the home
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Effective after bathing
Effective after exposure to water
Patents Pending
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Fast-acting
- Long-lasting
- Waterproof

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more
Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

April 2, 2014

Apply monthly (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your cat 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____
Second Dose _____
Third Dose _____

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Nylar® - Registered Trademark of McGlaughlin Gormley King Company

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Rodia, Carmen

From: Sweeney, Kevin
Sent: Tuesday, March 25, 2014 12:05 PM
To: Myers, Clayton; Rodia, Carmen; Gebken, Richard; McCall, Deborah
Subject: RE: Hartz conference call/discussion

Agreed

Kevin J. Sweeney, Senior Entomologist
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
+1 703.305.5063
sweeney.kevin@epa.gov

From: Myers, Clayton
Sent: Tuesday, March 25, 2014 12:04 PM
To: Rodia, Carmen; Gebken, Richard; McCall, Deborah
Cc: Sweeney, Kevin
Subject: Hartz conference call/discussion

Since I won't be able to attend this afternoon's call, here is a summary. Kevin, please clarify or correct if there is anything you disagree with. I'm trying to capture the main points of discussion for this particular product label:

1. Speed of kill claim. Given that statistical differences were shown at the 30 minute point, Kevin and I are fine with the 30 minute starts killing claim, formatted as was previously agreed with the footnote indicating this was true for 48 hours after the product was applied. "Starts killing new fleas within 30 minutes* *48 hours after application (or however we previously agreed to it—I might not have that correct verbatim"
2. Premise claims are not acceptable. Hartz is trying to argue that their product kills flea eggs that may fall off the animal and hatch into fleas in the home. The claims must focus on killing eggs on the animal. These products should not in any way imply that they protect any home or premise from flea infestations or affect flea survival in surrounding premises.

Clayton T. Myers, Ph.D
Entomologist/Biologist
U.S. Environmental Protection Agency
Office of Pesticide Programs

Phone: (703) 347-8874
Email: myers.clayton@epa.gov

I telework on Mondays and the second Friday of each pay period. When teleworking I can be reached at [REDACTED]

Personal privacy information

Rodia, Carmen

From: Rodia, Carmen
Sent: Tuesday, March 18, 2014 3:51 PM
To: SMcNear@hartz.com
Cc: McCall, Deborah; Gebken, Richard; Petrella, Carlyn; DJones@hartz.com
Subject: Regarding the FINAL Label Review Comments for EPA File Symbols 2596-RTI (Hartz Reference #143) and 2596-RTO (Hartz Reference #144)

Sean, as part of 2 separate e-mails sent out to Hartz's David Jones this afternoon, we have officially submitted to Hartz the Agency's FINAL label review comments and an e-copy of the efficacy review completed in support of the pending R315 new product applications for EPA File Symbols 2596-RTI (Hartz Reference #143) and 2596-RTO (Hartz Reference #144). As soon as Hartz incorporates the referenced FINAL label review comments into an amended master label for each of the 2 referenced applications, we will be able to out-process and register these new products. If you have any questions, please contact me directly. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

Decision Seq: 483629

Action Code: R315,NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUB

FFS Start Date: 22-Oct-2013

Tentative Ind: No

Start/Stop Clock

FQPA Clock:

Due Date: 22-Jul-2014

75-Day Due Date:

Days Elapsed:

OPP Target Due Date:

21-Day Due Date: 22-Oct-2013

FFS Original Decision:

Negotiated Due Date:

90-Day Due Date: 21-Jan-2014

Registrant

Response Due Date:

Predecisional Due Date: 08-Jul-2014

Add to Bundle?

Current Status: PENDING (24-Mar-2014)

Bundle ID:

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

Decision Bundle

75 Day Letters

45/90 Day Screen

Primary Decisions

Decision Milestone

FFS Negotiated Due Dates

OPP Target Due Date

Decision Comments

Payment

Unmatched Payments

Decision Ownership

Receipts

Data Package

Reduced Risk

Meetings & Milestones

FFS Information

Receipts	Staff Member	Reg/DCL Number	Submission Due Date	Response
S:948803	Petrella, Carlyn	2596-RTO	22-Jul-2014	PENDING
Submission of updated master label.				
S:941691	Petrella, Carlyn	2596-RTO	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
INITIAL APPLICATION.				

Viewing Record 1 of 1

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Rodia, Carmen

From: DJones@hartz.com
Sent: Saturday, March 22, 2014 4:14 PM
To: Rodia, Carmen
Cc: Petrella, Carlyn; SMcNear@hartz.com
Subject: EPA File Symbol 2596-RTO; Hartz Reference #144, Master label Mar. 22, 2014
Attachments: Master label Ref 144 EPA 2596-RTO Mar 22 2014.pdf

Dear Carmen,

This is the balance of our response to comments provided in the e-mails sent to Hartz on March 18. Many edits were implemented. For the edits we modified, supporting references ranging from PR Notices, recent stamped accepted labels and other citations are offered in support of the label text. These responses align to the e-mail comment numbers as presented in the March 18, 2014 e-mail for Hartz Ref. #144:

1. General Statements - EPA Strikeouts on label

- Page 4 - deleted hotline sentence from the label
- Page 5 and 6 - 3 months - 3 month duration claims have been retained. The recently stamped accepted master label for Hartz's similar product under EPA Reg. No. 2596-166 bear these claims (bottom of page 5 and the top of page 6) based on identical data and claims on the related precedent label for the original data submitter. Hartz's comparable label was very recently stamped accepted (Feb. 26, 2014) with the 3 month duration claims referencing the same data.
- Pages 7 and 8 - "home environment" and "premises" portion of claims. The EPA master stamped February 26, 2014 contains these claims (top of page 6, middle of page 8). The life cycle disruption efficacy data cited has and does support these statements.
- Page 6 - Adult tick "larvae" - According to our entomologist, the data supports the tick larvicidal claim. It has been retained on this label version. The EPA master stamped February 26, 2014 for EPA Reg. No. 2596-166, has this claim in the middle of page 6. The formulae are very similar.
- Page 8 - Triple "Action" - To clearly define the three actions we have added "kills", "repels" and "prevents".

2. Pet Spot On Mitigation Warnings (Front Panel) - This edit was implemented.

3. and 4. - Precautionary Statements - Label incorporates all changes stipulated.

5. Storage and Disposal - Language implemented in label as specified.

6. Optional/Alternate Label Text - "[Flea Eggs]" was added per the e-mail.

7. Optional/Alternate Label Text "New" - The phrase after the word "New" has been modified to be consistent with PR Notice 98-10 K.5. As this registration will be a new formula for Hartz with the addition of pyriproxyfen we contend it meets K.5. which allows "new" "...for a period of six months after EPA's approval of a revised or alternate formula and beginning when the product with this claim is first sold or distributed." This supports the new qualifying phrase of "*(claim to be removed 6 months after date product is first sold or distributed)*".

This label and above discussion are offered to facilitate a rapid conclusion. Please let me know if I can provide further support or information. Thank you for all your efforts in this application.

Sincerely,

David Jones

Manager Regulatory Affairs

The Hartz Mountain Corporation

400 Plaza Drive

Secaucus, NJ 07094

TEL: 201-271-4800 x 7414

FAX: 201-271-0357

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	<u>78.15%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 weeks and older, weighing 3 lbs. or more.

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

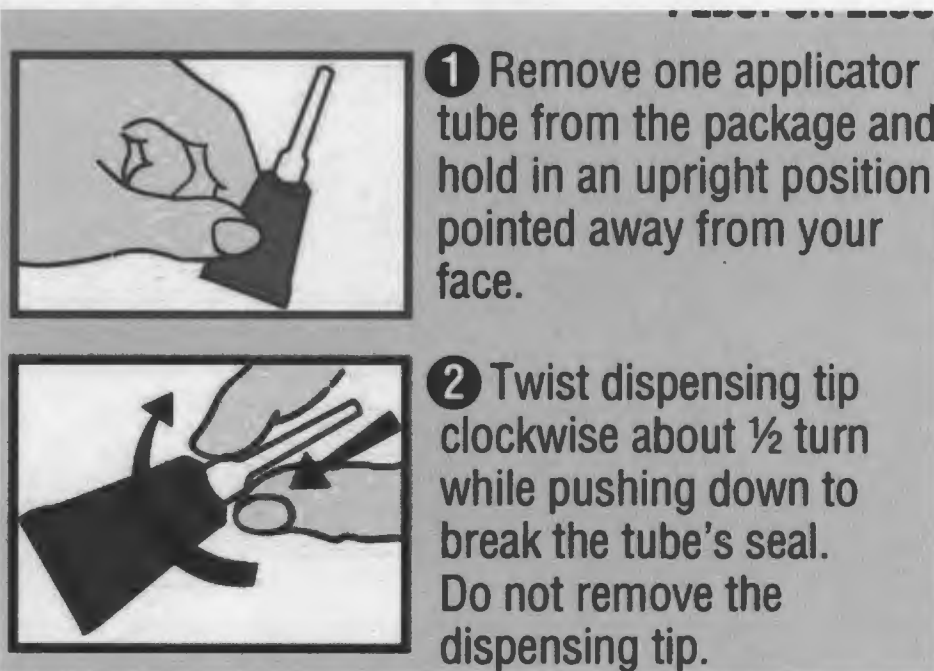
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS**

March 22, 2014

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

Prevents establishment of new infestations after application in the home environment

Prevents establishment of new infestations after application on premises

Prevents establishment of new infestations in the home environment

Prevents establishment of new infestations on premises

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Prevents flea eggs from developing into biting adults in the home environment (for) (up to) (30 days) (1 month) (4 weeks)
Prevents flea eggs from developing into biting adults (on premises) (for) (up to) (30 days) (1 month) (4 weeks)
Stays on and doesn't rub off
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation

March 22, 2014

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation in the home environment

Dual insect growth regulator (IGR) technology prevents re-infestation

Dual insect growth regulator (IGR) technology prevents re-infestation on premises

Contains two unique ingredients to prevent flea infestations

Contains two unique ingredients to prevent flea infestations in the home environment

Contains two unique ingredients to prevent flea infestations on premisesRapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Effective after bathing

Effective after exposure to water

Patents Pending

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

Kill(s) Repel(s) Prevent(s)

New (Formula) *(claim to be removed 6 months after date product is first sold or distributed)*

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more

Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose

First month, second month, third month

Value pack

3 month supply

March 22, 2014

3 monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your cat 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____
Second Dose _____
Third Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Nylar® - Registered Trademark of McGlaughlin Gormley King Company

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Rodia, Carmen

From: Rodia, Carmen
Sent: Tuesday, March 18, 2014 3:35 PM
To: DJones@hartz.com
Cc: McCall, Deborah; Gebken, Richard; Petrella, Carolyn; SMcNear@hartz.com
Subject: FINAL Label Review Comments for EPA File Symbol 2596-RTI (Hartz Reference #143)
Attachments: 2596-RTI -RTO, Efficacy Review (03-18-14).pdf; 2596-RTI (Harts Reference #143), E-Copy of Marked Up Label (03-18-14).pdf

David, in anticipation of stamping a "clean label" with no comments in support of the pending R315 new product registration for EPA File Symbol 2596-RTI (Hartz Reference #143), I have attached a revised "marked up" copy of the proposed master label as well as a list of FINAL label review comments that will need to be incorporated into an amended master label for out-processing this EXPEDITED new product application. This FINAL list of label review comments included changes necessary as part of the completed efficacy review (copy attached). As such, my FINAL label review comments are as follows:

General Statement(s):

1. Delete all text throughout the subject label that is marked with "~~strikethrough~~."

Pet Spot-On Mitigation Warning Statements (FRONT PANEL) section comment(s), bottom of page 1 of 10:

2. In order to address label clarity, you must revise the warning statements at the bottom of page 1 of 10 to read as follows:

"For use **ONLY** on dogs 8 weeks and older, weighing 5 to 22 lbs.
For use **ONLY** on dogs 8 weeks and older, weighing 23 to 44 lbs.
For use **ONLY** on dogs 8 weeks and older, weighing 45 to 88 lbs.
For use **ONLY** on dogs 8 weeks and older, weighing 89 to 132 lbs."

Pet Spot-On Mitigation Statement subsection comment(s), middle of page 2 of 10:

3. The 1.5 cm x 1.5 cm cat prohibition icon must be placed in a yellow box with **black images only**. If the box itself is yellow, a yellow and black cat prohibition icon may blend into the box.
4. Since the subject product contains fipronil, the existing pet spot-on mitigation statement "DO NOT USE ON CATS" listed at the middle left-hand side of page 2 of 10 is not complete. You must revise this pet spot-on mitigation statement to read as follows:

"DO NOT USE ON CATS
Keep cats away from treated dogs for
24 hours. If applied to or ingested by a cat, contact
your veterinarian immediately."

Precautionary Statements, Hazards to Humans subsection comment(s), bottom of page 2 of 10:

5. To facilitate inclusion of required label changes from the similarity clinic memo completed in support of this new product registration, you must revise this subsection to read "Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet."

Precautionary Statements, First Aid subsection comment(s), top of page 3 of 10:

6. In order to maintain consistency with other Hartz products, you must revise the 2nd sentence within the existing "**HOT LINE NUMBER**" subsection to read "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week."

Pet Spot-On Mitigation Statement subsection comment(s), bottom of page 3 of 10:

7. The 1.5 cm x 1.5 cm cat prohibition icon must be placed in a yellow box with **black images only**. If the box itself is yellow, a yellow and black cat prohibition icon may blend into the box.

8. Since the subject product contains fipronil, the existing pet spot-on mitigation statement "DO NOT USE ON CATS" listed at the bottom left-hand side of page 3 of 10 is not complete. You must revise this pet spot-on mitigation statement to read as follows:

"DO NOT USE ON CATS
Keep cats away from treated dogs for
24 hours. If applied to or ingested by a cat, contact
your veterinarian immediately."

Storage and Disposal section comment(s), top of page 5 of 10:

9. In order to maintain consistency with the product chemistry review that completed in support of this pending application for registration as well as the "**Physical or Chemical Hazards**" subsection at the bottom of page 2 of 10, you must insert the following text immediately following the existing 1st sentence to read "Do not use or store near heat or open flame."

Pet Spot-On Mitigation Warning Statements (TUBE TEXT) section comment(s), bottom of page 5 of 10:

10. In order to address label clarity, you must revise the warning statements at the bottom of page 5 of 10 to read as follows:

For use **ONLY** on dogs weighing 5 to 22 lbs. – 0.023 fl. oz. (0.67 ml.)
For use **ONLY** on dogs weighing 23 to 44 lbs. – 0.045 fl. oz. (1.34 ml.)
For use **ONLY** on dogs weighing 45 to 88 lbs. – 0.091 fl. oz. (2.68 ml.)
For use **ONLY** on dogs weighing 89 to 132 lbs. – 0.136 fl. oz. (4.02 ml.)"

Optional/Alternate Label Text section comment(s), middle of page 6 of 10:

11. In order to maintain consistency with the efficacy review that completed in support of this pending application for registration, you must make the following changes:

- Revise the proposed speed of kill claim to read as follows:

"Starts killing new fleas within 1 hour*
*48 hours after initial application"

- You may add the following text immediately following the 1st proposed optional marketing claim within the "[Flea Eggs]" subsection to read "(3 months)"

Optional/Alternate Label Text section comment(s), middle of page 9 of 10:

12. In order to maintain consistency with the draft Notice of Registration for this pending new product, revise the existing optional/alternate marketing claim "New (Formula) (***claim to be removed after 6 months***)" to read "New (Formula) (***claim to be removed 6 months following registration of this product***)"

As such, you must submit an amended master label which incorporates all of the above FINAL label review comments. If you have any questions, please call me directly. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

Hartz® Reference # 143

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)
First Defense Pro™ for Dogs (&) (and Puppies)
FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FRONT PANEL

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing 5 to 22 lbs.
Weighing 23 to 44 lbs.
Weighing 45 to 88 lbs.
Weighing 89 - 132 lbs.

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	81.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

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NET CONTENTS:

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



[Cat Warning: A cat prohibition icon will appear on the front panel and back panel.]

DO NOT USE ON CATS

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-275-1414 for human and

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veterinary health concerns, emergency medical treatment information or pesticide incidents.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER
DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS
DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT
DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS
THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER



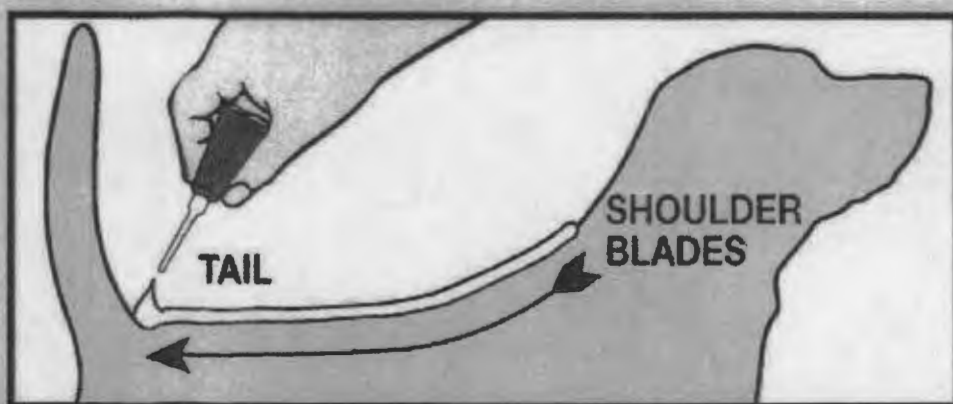
DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

SIDE EFFECTS

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

~~For more information, call 1-800-275-1414 (toll-free) or visit us online at www.hartz.com.~~

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

[Product name]

Only for use on DOGS AND PUPPIES 8 WEEKS OR OLDER

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

[Adult Fleas]

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (2 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (2 months) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (2 months)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (2 months) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (2 months)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (2 months) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of flea infestation in the home

Prevents establishment of flea infestation in the home

Prevents establishment of flea infestation in the home

Prevents establishment of flea infestation in the home

Prevents establishment of flea infestation in the home

Starts killing fleas within 30 minutes (mins) (and lasts for 30 days) (1 month) (4 weeks)

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

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Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

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Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home environment (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults on premises (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation

~~Dual insect growth regulator (IGR) technology prevents re-infestation in the home environment~~

~~Dual insect growth regulator (IGR) technology prevents re-infestation on premises~~

Contains two unique ingredients to prevent flea infestations

~~Contains two unique ingredients to prevent flea infestations in the home environment~~

~~Contains two unique ingredients to prevent flea infestations on premises~~

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

Waterproof

Effective after bathing

September 18, 2013

Effective after exposure to water
Easy spot on topical applicator
Patents Pending

Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

~~Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)~~

New (Formula) *(claim to be removed after 6 months)*

Only for dogs and puppies 8 weeks of age or older

Specially formulated for dogs and puppies 8 weeks of age or older

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

(Pro-cision Flo® Applicator)

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Hartz® Reference #143
EPA Reg. No.: 2596-
MASTER LABEL--

September 18, 2013

Second Dose _____
Third Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Rodia, Carmen

From: Rodia, Carmen
Sent: Thursday, March 13, 2014 11:30 AM
To: DJones@hartz.com
Cc: McCall, Deborah; Gebken, Richard
Subject: Preliminary Label Review Comments for EPA File Symbol 2596-RTO (Hartz Reference #144)
Attachments: 2596-RTO (Hartz Reference #144), E-Copy of Marked Up Label (03-13-14).pdf

David, in anticipation of stamping a "clean label" with no comments in support of the pending R315 new product registration for EPA File Symbol 2596-RTO (Hartz Reference #144), I have attached a "marked up" copy of the proposed master label as well as a list of preliminary label review comments that will need to be incorporated into an amended master label for out-processing this new product application. The only remaining review that we are waiting for at this point is the efficacy review. Once the efficacy review has been completed, I might have a number of final comments that might need to be incorporated into an even further master label. As such, my preliminary label review comments are as follows:

General Statement(s):

1. Delete all text throughout the subject label that is marked with "strikethrough."

Pet Spot-On Mitigation Warning Statement section comment(s), bottom of page 1 of 9:

2. In order to address label clarity, you must revise the last text statement at the bottom of page 1 of 9 to read "For use **ONLY** on cats & kittens 8 weeks and older, weighing 3 lbs. or more."

Precautionary Statements, Hazards to Humans subsection comment(s), top of page 2 of 9:

3. To facilitate inclusion of required label changes from the similarity clinic memo completed in support of this new product registration, you must revise this subsection to read "Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet."

Precautionary Statements, First Aid subsection comment(s), middle of page 2 of 9:

4. In order to maintain consistency with other Hartz products, you must revise the 2nd sentence within the existing "**HOT LINE NUMBER**" subsection to read "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week."

Storage and Disposal section comment(s), middle of page 4 of 9:

5. In order to maintain consistency with the product chemistry review that completed in support of this pending application for registration as well as the "**Physical or Chemical Hazards**" subsection at the top of page 2 of 9, you must insert the following text immediately following the existing 1st sentence to read "Do not use or store near heat or open flame."

Optional/Alternate Label Text section comment(s), middle of page 8 of 9:

6. In order to maintain consistency with the draft Notice of Registration for this pending new product, revise the existing optional/alternate marketing claim "New (Formula) (***claim to be removed after 6 months***)" to read "New (Formula) (***claim to be removed 6 months following registration of this product***)"

As such, you must submit an amended master label which incorporates all of the above preliminary label review comments. If you have any questions, please call me directly. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
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Washington, DC 20460-0001

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(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%

OTHER INGREDIENTS	78.15%
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TOTAL	100.00%
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KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 Weeks and older weighing 3lbs. or more.

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-275-1414 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS.**

DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

~~For more information, call 1-800-375-1414 (weekdays, 9 am - 5 pm
E.S.T.)~~

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

Sept. 23, 2013

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

~~Prevents establishment of new infestations after application in the home environment~~

~~Prevents establishment of new infestations after application on premises~~

~~Prevents establishment of new infestations in the home environment~~

~~Prevents establishment of new infestations~~

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks
(for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1
month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs ~~and larvae~~

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4
weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days)
(1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4
weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month)
(4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4
weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults in the home environment (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults (on premises) (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

~~Dual insect growth regulator (IGR) technology prevents re-infestation in the home~~

Dual insect growth regulator (IGR) technology prevents re-infestation

~~Dual insect growth regulator (IGR) technology prevents re-infestation in the home~~

Contains two unique ingredients to prevent flea infestations

~~Contains two unique ingredients to prevent flea infestations in the home~~

~~Contains the unique active ingredients to prevent flea infestation~~
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Effective after bathing
Effective after exposure to water
Patents Pending
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

~~Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)~~

New (Formula) (*claim to be removed after 6 months*)

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more
Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose
First month, second month, third month
Value pack
3 month supply
3 monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Nylar® - Registered Trademark of McGlaughlin Gormley King Company

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

From: Clayton Myers, Ph.D., Entomologist/Biologist

Date: March 18, 2014

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

2596-RTI

DP barcode: 417330

Decision no.: 483630

Submission no: 941688

Action code: R315

Product Name: Hartz Reference #143

EPA Reg. No or File Symbol: 2596-RTI

Formulation Type: Pet spot-on for dogs

Ingredients statement from the label with PC codes included: 9.80% fipronil (pc code 129121), 8.8% s-Methoprene (pc code 105402), and 0.25% Pyriproxyfen (pc code 129032).

Application rate(s) of product: Various, depending on pet weight class

OCSPP/OPPTS Guidelines: OPPTS 810.3300.

2596-RTO

DP barcode: 417293

Decision no.: 483629

Submission no: 941691

Action code: R315

Product Name: Hartz Reference #144

EPA Reg. No or File Symbol: 2596-RTO

Formulation Type: Pet spot-on for cats

Ingredients statement from the label with PC codes included: 9.80% fipronil (pc code 129121), 11.8% s-Methoprene (pc code 105402), and 0.25% Pyriproxyfen (pc code 129032).

Application rate(s) of product: Various, depending on pet weight class

OCSPP/OPPTS Guidelines: OPPTS 810.3300.

I. Action Requested: Review cited and submitted efficacy data to support the new product claims. Review labels.

II. Background:

The registrant is citing Merial data and submitting speed of kill studies in support of new pet stripe-on products for dogs and cats with claims against ticks, fleas, etc.

III. Study Reviews:

Cited MRIDs: 43577715, 43577716, 44942106, 45612701, 45618501, 45620501, 45620504, 45620505, 45620506, 45628101, 45628102, 45628103, 45628104, 45866901, 45866902, 46019201, 46019202,

The cited data included a number of titration, dosage, and efficacy studies for support of claims against fleas and ticks, etc. from Merial's database for the pioneer fipronil pet spot-on products. These studies are adequate to support killing and residual control claims against fleas, ticks, and other protection claims as listed on pioneer product labels, and as proposed on the submitted product labels. Speed of kill claims are not addressed by this cited data. No claims are supported beyond those approved for pioneer fipronil pet spot-on products.

MRIDs 49115604 and 49115704 contain data for speed of kill adulticide claims against fleas that apply to both products cats and dogs, respectively

MRID 49115604. Everett, W.R. Speed of Kill Efficacy of a Dermal Treatment Applied to Cats Against Cat Fleas (*Ctenocephalides felis*). March 26, 2013.

Description: This was a GLP study (with 2 noted exceptions) designed to evaluate the speed of kill of adult fleas for a stripe-on fipronil product applied at 0.50 ml test substance/test animal. Cats were ranked by flea retention and then randomly assigned to either a control or treatment group. 16 total cats, with weights varying from 6-13 lbs were used for the study. Speed of kill was assessed 2 days after application of treatments to animals. 100 fleas were placed on each cat, along the lateral mid-line of the animal. Flea removal was done with combs after each infestation at the various test times and mortality was assessed. Flea counts were log transformed and analyzed using a student's t-test. Mortality was calculated using Abbott's formula applied to geometric means.

Results: Control mortality exceeded 10 percent for every reading in the study, and was greater than 20% for the 15 minute reading. Mortality after 15 minutes was 0.0% and was not significantly different from the control. Mortality at 30 minutes was 3.4% and was not significantly different than the control. Mortality was 13.7% at 1 h and was not significantly different than the control. Mortality exceeded 25% at 2 hours, as the value was calculated to be 37.5%, which was significantly different than the control. However for this 2 h reading, control mortality was nearly 18%.

Conclusion: Due to insignificant mortality observations for most readings and excessive control mortality at the 2 hour reading, no speed of kill claims are supported for the cat product, 2596-RTO.

MRID 49115704. Everett, W.R. Speed of Kill Efficacy of a Dermal Treatment Applied to Dogs Against Cat Fleas (*Ctenocephalides felis*). March 26, 2013.

Description: This was a GLP study (with 2 noted exceptions) designed to evaluate the speed of kill of adult fleas for a stripe-on fipronil product applied at 0.030 ml test substance/lb test animal. Dogs were ranked by flea retention and then randomly assigned to either a control or treatment group. 16 total dog of mixed breed, with weights varying from 15-27 lbs were used for the study. Speed of kill was assessed 2 days after application of treatments to animals. 100 fleas were placed on each dog, along the lateral mid-line of the animal. Flea removal was done with combs after each infestation at the various test times and mortality was assessed. Flea counts were log transformed and analyzed using a student's t-test. Mortality was calculated using Abbott's formula applied to geometric means.

Results: Control mortality only exceeded 10 percent for the 48 hour reading, and was less than 15%. Mortality after 15 minutes was 3.1% and was not significantly different from the control. Mortality at 30 minutes was 11.8% and was significantly different than the control. Mortality exceeded 25% at 1 hour, as the value was calculated to be 68.5%, which was significantly different than the control.

Conclusion: Based upon a threshold of 25% to support a claim of starts killing, the data is adequate to support the following footnoted claim only on the dog product, 2596-RTI: "starts killing new fleas within 1 hour*, *48 hours after initial application."

IV. ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

The proposed label efficacy claims are acceptable except for the comments and recommendations below:

A. For both products, killing claims against flea adults are only acceptable up to 30 days. Claims against breaking the flea life cycle or controlling flea eggs, and larvae up to 3 months are acceptable, but not adult control claims, or 3 month durations on the "general" flea claims as listed. This product is intended to be applied monthly, so the claim should not imply that this product will continue to kill re-infesting adult fleas after 30 days.

B. For the dog product only, 2596-RTI: The speed of kill claim for fleas must be revised as follows to include a footnoted claim: "starts killing new fleas within 1 hour*, *48 hours after initial application."

C. For the cat product, 2596-RTO, no speed of kill claims are supported.

D. For both products, remove claims stating that the product "prevents re-infestations/infestations in the home environment, premises etc." This claim implies that a pet applied product can control pests on premises, which is not supported. All variations of this claim pertaining to home premise infestations must be removed. Claims of killing flea eggs that may develop into adult fleas or preventing infestations by killing eggs on the animal are acceptable.

IV. VETERINARIAN'S COMMENTS AND RECOMMENDATIONS

The following comments are acceptable claims for the comments and recommendations.

A few days after applying the product, the adult fleas are only seen up to 30 days. Claims against fleas are the best for controlling flea eggs and larvae up to 30 days. The product is effective and has a long duration of action. The product is effective and has a long duration of action. The product is effective and has a long duration of action.

It is the dog product only. The product is effective and has a long duration of action. The product is effective and has a long duration of action. The product is effective and has a long duration of action.

A few days after applying the product, the adult fleas are only seen up to 30 days. Claims against fleas are the best for controlling flea eggs and larvae up to 30 days. The product is effective and has a long duration of action. The product is effective and has a long duration of action. The product is effective and has a long duration of action.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 10, 2014

NOTE TO RM 10 Carlyn Petrella

SUBJECT: Certification to Compliance with Child-Resistant Packaging Regulations EPA
Registration Number: 2596-RTO DP 417292, Decision # 483629

Please note that EPA FILE NO: 2596-RTO (cat product) certification regarding child-resistant packaging (CRP) has been reviewed **and is acceptable** regarding compliance with the standards of 40 CFR 157.32. Acceptance of the CRP certification is based on the results for 0.5ml, 0.67ml, 1.34ml, 2.68, and 4.02ml sizes see MRID 48684601, 48684602, 48684603, 48684604, 48684605, and 48684606 in review by Breann Hanson March 29, 2012 [DP3999060, 399061, 399062, 399063; EPA Reg. No. 2596-RAG, 2596-RAU, 2596-RAL, and 2596-RAA]. The label dated September 23, 2013 on page 3 has the same directions for using the CRP as were used in Senior Adult Use Effectiveness (SAUE) testing per the Breann Hanson March 29, 2012 review as noted above.

Please place a copy of this note in the registration jacket for the above named product. Please advise the registrant that this **CRP certification is acceptable**. If you have any questions please contact me at (703)-308-7368.

A handwritten signature in cursive script, reading "Rosalind L. Gross", is positioned above the typed name.

Rosalind L. Gross



OK

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

CHILD RESISTANT PACKAGING CERTIFICATION STATEMENT
Title 40 part 157 subpart B

Registrant Name and Address:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Products:

Hartz Reference # 144, EPA Reg. No. 2596- RTO

I certify that the packaging that will be used for the products listed above meet the standards of 40 CFR 157.32.

Sean McNear
Sr. Director Regulatory Affairs
& Quality Assurance

Date



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 417291; FILE SYMBOL No.: 2596-RTO; DECISION No.: 483629;
PC Code(s): 129121, 129032, 105402, Action Code: R 315; FOOD Use: No

DATE: March 7, 2014

SUBJECT: Hartz Reference #144 (Cat product)

FROM: Akiva Abramovitch, Ph.D.
Technical Review Branch / RD (7505P)

THROUGH: Shyam Mathur, Ph.D.
Product Chemistry Team Leader
Technical Review Branch / Registration Division (7505P)

TO: Carlyn Petrella / Richard Gebken, PM 10
Insecticide Branch / Registration Division (7505P)

Company Name: The Hartz Mountain Corporation
Formulation Type: Liquid Insecticide

INTRODUCTION:

The applicant petitioned for a new non-food end use product registration. In support of the application, the applicant submitted product chemistry data corresponding to guideline 830 series, group A & group B. The product chemistry data for the proposed product have been submitted under MRID: 491156-01 through 03.

TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF dated March 11, 2014 (replaces the April 4, 2013 CSF).

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.80%), Methoprene (11.80%) and Pyriproxyfen (0.25%).
2. All of the source materials of the active ingredients are derived from registered sources.
3. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses.
4. Confidential Statement of Formula(s):

[X] Basic CSF Dated: March 11, 2014 (replaces the April 4, 2013 CSF).

DP BARCODE No.: 417291; FILE SYMBOL No.: 2596-RTO; DECISION No.: 483629;
PC Code(s): 129121, 129032, 105402, Action Code: R 315; FOOD Use: No

5. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

☒ Yes, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

Flammable/Combustible

"Do not use or store near heat or open flame" correctly stated on the label.

Is the sub statement in compliance with PR Notice 97-6? ☒ Yes, if not, explain below:

- d. Label requires an additional Storage and Disposal statement: ☒ Yes ☐ No; if yes explain below:

Flammable/Combustible

"Do not use or store near heat or open flame" correctly stated on the label.

DP BARCODE No.: 417291; **FILE SYMBOL No.:** 2596-RTO; **DECISION No.:** 483629;
PC Code(s): 129121, 129032, 105402, **Action Code:** R 315; **FOOD Use:** No

6. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	491156-02
830.1600	Description of materials used to produce the product		X		A	491156-02
830.1650	Description of formulation process		X		A	491156-02
830.1670	Discussion on the formation of impurities		X		A	491156-02
830.1700	Preliminary analysis		X		A	491156-02
830.1750	Certified limits (158.350)	Standard certified limits	X		A	
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	491156-03

A = Acceptance, N = Not Acceptable, G = Data Gap,
W = Waiver Request, I = In Progress, NA = Not Applicable

DP BARCODE No.: 417291; **FILE SYMBOL No.:** 2596-RTO; **DECISION No.:** 483629;
PC Code(s): 129121, 129032, 105402, **Action Code:** R 315; **FOOD Use:** No

7. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Light yellow liquid	A	491156-01
830.6315	Flammability	Flammable-Flash point 45C	A	491156-01
830.6316	Explodability	None- stable at normal and elevated temperatures	W	491156-01
830.7000	pH	7.4	A	e-mail attachment
830.7300	Density (units)	8.28 lb/gal at 25 C	A	491156-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. Basic CSF dated March 11, 2014 is acceptable.
2. The registrant must submit Storage Stability and Corrosion data to support the registration of this product.

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Sent to: **Mr. David Jones, Hartz Corp.**
 Street, Apt. No. or PO Box No.: **400 Plaza Drive**
 City, State, ZIP+4: **Secaucus, NJ 07094-3088**
 PS Form 3800, August 2006 See Reverse for Instructions

SENDER: COMPLETE THIS SECTION

Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
 Print your name and address on the reverse so that we can return the card to you.
 Attach this card to the back of the mailpiece, or on the front if space permits.

1. Name Addressed to:
Mr. David Jones
Manager for Regulatory Affairs
The Hartz Corporation
400 Plaza Drive
Secaucus, NJ 07094-3088

COMPLETE THIS SECTION ON DELIVERY

2. Signature: *[Signature]* ☐ Agent ☐ Addressee
 Received by (Printed Name): **[Signature]** Date of Delivery: **JAN 28 2007**
 Is delivery address different from item 1? ☐ Yes ☒ No
 If YES, enter delivery address below: ☐ No

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☒ Certified Mail ☐ Express Mail
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• Sender: Please print •
Ms. Carlyn Petrella
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001 Room # **37232**
(EPA Reg. No. 25.96-RTD)
 P+4 in this box •



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Thursday, January 16, 2014

CERTIFIED MAIL: (Article Number 7008 3230 0000 9482 5403)

OPP Decision Number: D-483630

Mr. David Jones
Manager for Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Data Deficiency
EPA File Symbol: 2596-RTO
Product Name: Hartz Reference #144
Application Date: September 24, 2013
EPA Receipt Date: September 25, 2013

Dear Mr. Jones:

The application referred to above has been determined, pursuant to 40 CFR §152.105, not to be sufficiently complete to process. Therefore, your application is considered deficient. Citations for specific acceptable companion animal safety data, a CRP certification, and a revised data matrix, as specified in detail below, must be submitted to the Agency within 75 days of the date of this letter, before the processing of the application can be continued. **Upon receipt of the revised information, EPA will require a renegotiated PRIA due date that will allow the Agency sufficient time to complete the review process for this product.**

If, after 75 days, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion as noted below, the Agency will terminate any action on this application and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to this application must be submitted as a new application. The noted deficiencies for the referenced R310 new product; non-fast track application are as follows:

1. Specific companion animal safety data citations were not cited on the data matrix submitted along with this application. You must cite specific acceptable companion animal safety data by MRID along with a revised data matrix in order to support this application, or withdraw this application. Further review of this application cannot be made until the above deficiency has been resolved.
2. On the data matrix submitted with this application, you did not cite specific acceptable companion animal safety data that are needed to support this application. You must revise the data matrix by listing specific acceptable citations for companion animal safety data by MRID. Further review of this application cannot be made until the above deficiencies have been resolved.

For reference purposes, the timeline for your re-submission is as follows:

Tuesday, April 1, 2013: Revisions of all items identified in items #1 through #2 above must be provided to the Agency to further process this application. If you have not responded, or you subsequently failed to complete the

application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn.

Please contact either Ms. Carlyn R. Petrella at 703-347-0439 or via e-mail at Petrella.Carlyn@epa.gov or Mr. Richard J. Gebken at 703-305-6701 or via e-mail at Gebken.Richard@epa.gov directly during the hours of 9:00 am to 5:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Richard J. Gebken", written in a cursive style.

Richard J. Gebken,
Product Manager (10)
Insecticide Branch,
Registration Division (7504P)

002596-00RTI D483630



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 11, 2013

SIMILARITY CLINIC MEMORANDUM

Subject: Name of Pesticide Product: HARTZ[®] REFERENCE #144
EPA Reg. No. /File Symbol: 2596-RTO
DP Barcode: DP416012
Decision No.: 483629
Submission #: 941691
Action Code: R315
PC Codes: 129121 (Fipronil: 9.80%)
105401 (S-Methoprene: 11.80%)
129032 (Pyriproxyfen: 0.25%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Dec - 11 - 2013
JCR

To: Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORPORATION

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	by wt.
129121 Fipronil	9.80%
105401 (S)-Methoprene	11.80%
129032 Pyriproxyfen	0.25%
<u>Other Ingredients:</u>	78.15%
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

"Similarity clinic..."

BACKGROUND:

According to the Application for Registration (dated September 24, 2013): "PRIA Submission R315; New product registration application. Previously submitted and rejected under File symbol 2596-RTA." The registrant is not claiming similarity to an existing product. The registrant has included a data matrix (dated September 24, 2013) which cites the following MRIDs to satisfy the acute toxicity data requirements: 44942004 (acute oral LD₅₀); 44942005 (acute dermal LD₅₀); waiver requested (acute inhalation LC₅₀); 44942006 and 48405805 (primary eye irritation); 44942007 (primary dermal irritation); and 44942008 (dermal sensitization). The cited companion animal safety studies (870.7200) are: 44942104, 45612702, 45620507, and waiver requested. The proposed label has the signal word CAUTION and states that the product is to be used only on cats and kittens 8 weeks or older and weighing 3 or more pounds. The product would be in application tubes, with one application consisting of 0.017 fl. oz. or 0.5 mL. In addition, there is a basic CSF dated 4/4/13.

COMMENTS AND RECOMMENDATIONS:

1. According to OPPIN, 5 of the cited acute toxicity studies (MRIDs 44942004, 44944942006, 44942007 and 44942008) were originally submitted to support 65331-4, and one study (48405805) was originally submitted to support 2596-167, -168, and -169.
2. After comparing the CSF of 65331-4 with the CSF (dated 4/4/2013) for 2596-RTI, TRB concludes that the acute toxicity (and companion animal safety) studies that were used to support the registration of 65331-4 will also support the registration of 2596-RTO. The presence of 0.25% pyriproxyfen [which has low toxicity to mammalian species] in 2596-RTO is not significant in terms of acute toxicity, so that studies conducted on the formulation for 65331-4 (which lacks pyriproxyfen) can be used to define the acute toxicity of 2596-RTO. MRID 44942004 satisfies the acute oral LD₅₀ requirement (with assignment to toxicity category III); 44942005 satisfies the acute dermal LD₅₀ requirement (with assignment to toxicity category IV); 44942006 [with the additional information in MRID 48405805, as noted below] satisfies the eye irritation study requirement (assignment to toxicity category III); 44942007 satisfies the dermal irritation study requirement (toxicity category IV); and 44942008 satisfies the dermal sensitization study requirement (not a sensitizer).
3. The eye irritation study in MRID 48405805 was conducted on a formulation containing the following: Etofenprox – 55%; Piperonyl butoxide – 10%; MGK 264 – 1%; Methoprene – 2.3%; Nylar – 1%; other ingredients – 30.7%. *While this citation in itself does not satisfy the eye irritation study data requirement for the registration of 2596-RTO which has a label declaration of 9.8% fipronil, 8.8% methoprene and 0.25% pyriproxyfen, the registrant has stated in a cover letter dated September 24, 2013 that this study has been cited because it contains an inert which is also present in 2596-RTO. Based on the cited study in MRID 44942006, as well as the additional information in 48405805, 2596-RTO is assigned to Toxicity Category III for eye irritation.*

4. The study in MRID 44942009 [Clery, D. (1999) Fipronil/(S)-Methoprene/Topical/Solution/Target Species Safety Study in the Cat: Interim Final Report: Lab Project Number: GB011/99-001: PR&D 0023301. Unpublished study prepared by Biological Labs. Europe Ltd. 127 p. {OPPTS 870.7200}] was reviewed (TXR 5001487, memorandum for 65331-U dated April 12, 2000) with the following comments:

“...Fipronil/s-Methoprene solution for cats (Active Ingredients: Fipronil: 10% w/v; (S)-methoprene: 12% w/v) was topically applied at dose levels of 0.5 mL (1X), 1.5 mL (3X) or 2.5 mL (5X times the maximum recommended dose) to groups of 6 male and 6 female kittens (52-59 days old at the initiation of the study). Controls were not dosed. Animals were treated on Study Day 0 and again on Study Day 28. The report includes results of the study up to Day 42...

“Overall, no treatment-related, biologically-significant effects on body weight, clinical biochemistry, or hematology, were reported. Although there were statistically-significant changes in hematology and clinical chemistry parameters in some treatment groups at some sampling times...none of the changes followed a clear dose-response relationship and most were within the normal reference range...there was no evidence of toxicity in any of the animals... The final dosages, as indicated on the label or as packaged in the applicator tubes, must be consistent with (no more than) the 1X application rate in this study (0.5 mL). With this stipulation and assuming that there are no additional adverse effects reported in the final report, the study is classified as **Acceptable/Guideline** for a companion animal safety study (OPPTS 870.7200) in cats (kittens).”

5. Based on the day 0 mean body weights of the 5X (2.5 mL) kittens and the absence of toxicity in this group in the study in MRID 44942009 we can accept a minimum weight of 3 lbs as proposed on the label for 2596-RTO.
6. The study in MRID 44942104 [Nolan-Smith, S. (1999) Fipronil/(S)-Methoprene Topical Solution: Target Species Safety Study in the Dog: Interim Report: Lab Project Number: 1686/2: 1686/2-D1142: PR&D 0002101. Unpublished study prepared by Covance Laboratories Ltd. 266 p. {OPPTS 870.7200}] was conducted on dogs and cannot be used to support the use of 2596-RTO on cats.
7. The companion animal safety study in MRID 45612702 [Nolan-Smith, S. (2001) To Investigate the Safety of a Topical Formulation Containing ML-2,095,988 509T in Dogs Weighing Approximately 2kg (+/-1.5kg) at One, Three and Five Times the Maximum Label Recommended Dosage: Final Report: Lab Project Number: 1686/12: 1686/12-D2160: PR&D 0045801. Unpublished study prepared by Covance Laboratories. 324 p.] was conducted on dogs and cannot be used to support the use of 2596-RTO on cats.
8. The companion animal safety study in MRID 45620507 [Godin, C.; Alva, R. (2000) ML-2,095,988 509T/Dog/Solution/Topical/Safety/Tolerance/Reproduction, Reactions: Final Report: Lab Project Number: PR&D 0020201: WEL 99885: PR&D 00202. Unpublished

study prepared by White Eagle Toxicology Laboratory. 123 p.] was a special reproductive study conducted on dogs and cannot be used to support the use of 2596-RTO on cats.

9. *The registrant should cite MRID 42178309 [Chapman, E. (1991) S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Lab Project Number: 91/0776. Unpublished study prepared by Life Science Research Ltd. 320 p.] in the data matrix under 870.7200 as none of their companion animal safety study citations addresses the low subchronic (or chronic) toxicity of pyriproxyfen (nylar) to mammalian species. With the citation of MRID 42178309 under 870.7200 as supporting data, all acute toxicity and companion animal safety data requirements for the registration of 2596-RTO will be satisfied.*
10. We can accept a waiver request for the inhalation toxicity study requirement, with assignment of 2596-RTI to toxicity category IV by this exposure route.
11. Based on the cited acute toxicity studies, 2596-RTO has the following acute toxicity profile:

Acute oral LD ₅₀ (rat)	Toxicity category III	44942004 (cited)
Acute dermal LD ₅₀ (rat)	(Toxicity category IV)	(44942005)
Acute inhalation LC ₅₀	Toxicity category IV	Waived
Primary eye irritation	Toxicity category III ^a	44942006, 48405805 ^a (cited)
Primary dermal irritation	Toxicity category IV	44942007 (cited)
Dermal sensitization	Not a sensitizer	44942008 (cited)

^aAssigned to Toxicity category III on the basis of information in MRIDs 44942006 and 48405805.

12. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 2596-RTO, as obtained from the Label Review System:

PRODUCT ID #: 002596-00179

PRODUCT NAME: HARTZ® REFERENCE #144

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.

-Do not give anything to an unconscious person.

If in eyes:

-Hold eye open and rinse slowly and gently with water for 15-20 minutes.

-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

21-Day Screen Completed by
Contractor

21-Day Expires on 10-16-13

Jacket # 2596-RTO

MRID# 492229

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHABLE

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 9-25-13

Experts In-Processing Signature: B.B.

Date 9-27-13

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2596-R10</u>		EPA Receipt Date: <u>9-25-13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

- * Deficiencies in submitted studies: Did not include a Data confidentiality claim statement in MRID: 492229-01
- * Inserts approved for non-food use
- * Emailed submitter 10/28
- * Corrections received 10/29
- * submitted studies PASSED PRN 11-3 review
- * Jacket PASSED

Wk

MRID: 492229

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Correa, Leah

From: DJones@hartz.com
Sent: Tuesday, October 29, 2013 3:15 PM
To: Correa, Leah
Cc: Ashe, Anthony
Subject: Re: Submission to EPA: Products Hartz Reference #143 and Hartz Reference #144 (EPA Reg# 2596-RTI and 2596-RTO)
Attachments: No Data Conf Claims forms Hartz Ref 143 and 144 2013 Oct 29.pdf

Leah,

Per our discussion I have prepared a second page for each volume 2 submission listed below. I appreciate your taking the time to help me understand the requirement for waivers and options. Attached please find the scans of signed pages claiming no data confidentiality. They are scans of very similar forms with identical pagination and are intended one each for the volumes as the second page.

Thank you for your e-mail and taking the time to discuss the issues.

Sincerely,

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Correa, Leah" <Correa.Leah@epa.gov>
To: "djones@hartz.com" <djones@hartz.com>,
Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>
Date: 10/28/2013 05:24 PM
Subject: Submission to EPA: Products Hartz Reference #143 and Hartz Reference #144 (EPA Reg# 2596-RTI and 2596-RTO)

Good Afternoon, Mr. Jones:

This e-mail is to address an issue found in the submitted studies associated with your applications for the registration of the products Hartz Reference #143 and Hartz Reference #144 (EPA Reg# 2596-RTI and 2596-RTO):

Hartz Reference # 143 (2596-RTI)

MRID 492230-01: Volume 2 – Supplemental Information: Product: HARTZ Reference #143

- You must include an acceptable statement of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study.

Hartz Reference # 144 (2596-RTO)

MRID 492229-01: Volume 2 – Supplemental Information: Product: HARTZ Reference #144

- You must include an acceptable statement of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study.

Please verify and send the corrections either by e-mail or through our secure fax line as soon as possible. If you have any questions, please do not hesitate to contact me.

Best Regards,

Leah

Leah M. Correa - EPA Contractor

2777 S. Crystal Drive, S-4811, Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 27, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-483629
EPA File Symbol or Registration Number: 2596-RTO
Product Name: HARTZ REFERENCE # 144
EPA Receipt Date: 25-Sep-2013
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORPORATION

DAVID JONES
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE
TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR
ONLY;;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST
EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

No additional payment is due at this time. The Office of Pesticide Programs will make a determination on your discretionary refund request just prior to the time when a decision on this application is made.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{9416913~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S-

941691

EPA File Symbol/Reg. No.

2596-RTO

Pin-Punch Date:

9/25/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R315

Granted: R315

Amount Due: \$ 8,000

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐

Uncleared Inert in Product

Reviewer: Steve Schauble

Date: 9/26/13

Remarks:

*submission of new product previously rejected under Tech
defining screen (sim clinic, B. Beckus reviews)
discretionary refund requested (Mick) similarity clinic*

Receipt for Section 3

S: 941691

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 2596 THE HARTZ MOUNTAIN CORPORATION V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 2596-RTO Product Name: HARTZ REFERENCE # 144

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 24-Sep-2013

OPP Rec'vd Date: 25-Sep-2013

Front End Date: 26-Sep-2013

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for new registration

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

Hartz®

THE HARTZ MOVIE CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

No.

323922

DATE: 19-SEP-13

VENDOR NAME: US ENVIRONMENTAL PROTEC

VENDOR NO: 1992

INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
2596-CAT	18-SEP-13	1000081504 P-	0.00	8,000.00

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT.

Thank You!

0.00

8.000,00

THIS CHECK IS PROTECTED BY A VOID PANTOGRAPH, MICROPRINT SIGNATURE LINE AND A HEAT SENSITIVE PADLOCK ICON. ADDITIONAL SECURITY FEATURES ARE LISTED ON BACK

Hartz:

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS NJ, 07094

Bank of America

64-1278
611 GA

No. 323922

CHECK DATE
19-SEP-13

CHECK NUMBER
323922

CHECK AMOUNT
*****8,000.00

PAY Eight Thousand Dollars And 00 Cents *****

**TO
THE
ORDER
OF**

US ENVIRONMENTAL PROTECTION AGENCY
PESTICIDE REGISTRATION SERVICE FEE
PO BOX 979031
ST LOUIS, MO 63197-9000

1

8





United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-	2. EPA Product Manager Mr. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) The Hartz Mountain Corp./Hartz Reference #144	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Submission R315; New product registration application. Previously filed under File symbol 2596-RTA. MRIDs from data filed with that action cited herein.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. varies	No. per container see label
If "Yes" Package wgt		No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container see label	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product Printed <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other on doses	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Jones	Title Mgr Regulatory Affairs	Telephone No. (Include Area Code) (201) 271-4800
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager Regulatory Affairs	
Typed Name David Jones	5. Date Sept. 24, 2013	



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

September 24, 2013

FedEx Delivery

Document Processing Desk (Distribution Code-REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: New Pesticide Product Application, Hartz Reference #144

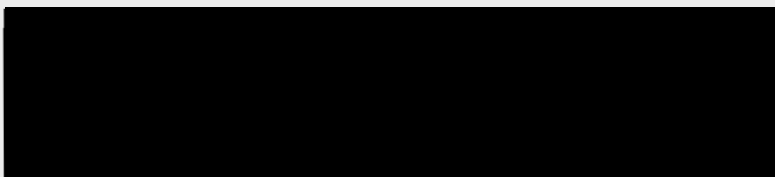
Dear Sir/Madam,

Enclosed please find a resubmission of a pesticide registration application package for Hartz Reference #144. This is an application previously submitted and rejected under EPA file symbol 2596-RTA. The label has been modified per direction from the agency. The Companion Animal Safety Study (CASS) citations have been expanded, an acute inhalation toxicity waiver request substantiation has been added, an acute eye toxicity study reference (Hartz's) and justification for a limited set of chemistry data waiver requests appended.

We have also included additional information on one inert that was discussed with EPA Staff on September 5, 2013. The cited data is submitted to support the use of the one inert as follows:

New formulas represented by 2596- RTA and RTL have been submitted to EPA for review. These formulas contain the inert ingredient [REDACTED]. Acute toxicity tests cited to support these formulas are based on formulas that do not contain this inert ingredient. To support the acceptable use of [REDACTED] in these formulas, a previously registered formula containing [REDACTED] at a significantly higher level (EPA Reg # 2596-169) was tested for acute eye irritation resulting in acceptable findings (Category III or higher). The MRID number for this study is 48405805.

Considering the amount of [REDACTED] in this formula, the following comparison of formula content is presented:



Given the significantly lower concentration of [REDACTED] for 2596-RTA and 2596-RTL vs 2596-169, no increase in toxic response from [REDACTED] is anticipated vs results for EPA Reg # 2596-169.

Inert ingredient information may be entitled to confidential treatment

Hartz Reference #144

September 24, 2013

Page 2

Enclosed is check no. 323922 payable to the US Environmental Protection Agency in the amount of \$8000. This is to cover the PRIA Code R315. Per instruction from Marty Monell, we respectfully request a partial refund of the fee previously paid for the initial filing (see meeting notes in Volume 2). Discussed in the same meeting evidenced in the attached summary we request an accelerated processing of this application. Consideration of this question is appreciated.

Direct contact by phone or e-mail is welcomed if I can assist in the processing of information presented in this package.

Sincerely,



David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
(201) 271-4800, ext. 7414
djones@hartz.com

Encl.

Volume 2 Supplemental Information (3 copies)

Summary of Meeting with EPA Sept. 5, 2013

Waiver Request, Scheuplein

Waiver Request, Hauswirth

Acute Inhalation Toxicity Waiver Request

Chemistry Data Waiver Requests



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address The Hartz Mountain Coporation 400 Plaza Drive Secaucus, NJ 07094	EPA File Symbol/Registration Number 2596-RTA
	Product Name Hartz Reference # 144
	Date of Confidential Statement of Formula (EPA Form 8570-4) 04/04/2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil, (S)-methoprene, Pyriproxfen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement.

That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil; CAS #122068-37-3	[REDACTED]	[REDACTED]
(S)-Methoprene; CAS # 65733-16-6	[REDACTED]	[REDACTED]
Pyriproxfen; CAS # 095737-68-1	[REDACTED]	[REDACTED]
Signature 	Name and Title Sean McNear, Sr. Dir. Reg Affairs	Date 05/13/2013

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094, 201-271-4800	EPA Registration Number/File Symbol 2596-
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-Methoprene and Pyriproxfen	Date April 30, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Residential	Product Name Hartz Reference #144

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date April 30, 2013	Typed or Printed Name and Title Sean McNear, Sr. Director Regulatory Affairs
--	------------------------	---



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date	Sept. 24, 2013	EPA Reg. No./File Symbol	2596-	Page 1 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Treatments to Control Pests of Humans and Pets	43577716	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45618501	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628101	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628102	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628103	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45628104	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	46019201	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	46019202	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	49115604	Hartz	Own	
830.1550	Product Identity and Composition	49115602	Hartz	Own	
Signature <i>David Jones</i>			Name and Title David Jones Manager Regulatory Affairs		Date Sept. 24, 2013 197




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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date	Sept. 24, 2013	EPA Reg. No./File Symbol	2596-	Page 2 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144		

Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1600	Description of Materials Used to Produce the Product	49115602	Hartz	Own	
830.1620	Description of the Production Process	49115602	Hartz	Own	
830.1650	Description of the Formulation Process	49115602	Hartz	Own	
830.1670	Discussion of Formation of Impurities	49115602	Hartz	Own	
830.1700	Viscosity	49115601	Hartz	Own	
830.1750	Certified Limits	49115602	Hartz	Own	
830.1800	Enforcement Analytical Method	49115603	Hartz	Own	
830.6302	Color	49115601	Hartz	Self-certification	
830.6303	Physical State	49115601	Hartz	Self-certification	
830.6304	Odor	49115601	Hartz	Self-certification	
Signature 			Name and Title David Jones Manager Regulatory Affairs		Date Sept. 24, 2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX


Date	Sept. 24, 2013	EPA Reg. No./File Symbol	2596-	Page 3 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/Reduction Chemical Incompatibility	Waiver			
830.6315	Flammability	49115601	Hartz	Self-certification	
830.6316	Explosibility	Waiver			
830.6317	Storage Stability	To be submitted	Hartz	In progress	
830.6319	Miscibility	49115602	Hartz	Own	
830.6320	Corrosion Characteristics	To be submitted	Hartz	In progress	
830.6321	Dielectric Breakdown Voltage	Waiver			
830.7000	pH	Waiver			
830.7300	Density/Relative Density/Bulk Density	49115601	Hartz	Own	
870.1100	Acute Oral Toxicity	44942004	Merial	Pay	
Signature			Name and Title David Jones Manager Regulatory Affairs	Date Sept. 24, 2013	



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Date	Sept. 24, 2013	EPA Reg. No./File Symbol	2596-	Page 4 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Toxicity	44942005	Merial	Pay	
870.1300	Acute Inhalation Toxicity	Waiver requested	Waiver		
870.2400	Acute Eye Irritation	44942006	Merial	Pay	
870.2400	Acute Eye Irritation	48405805	Hartz	Own	
870.2500	Acute Dermal Irritation	44942007	Merial	Pay	
870.2600	Skin Sensitization	44942008	Merial	Pay	
870.7200	Companion Animal Safety	44942009	Merial	Pay	
870.7200	Companion Animal Safety	44942104	Merial	Pay	
870.7200	Companion Animal Safety	45612702	Merial	Pay	
870.7200	Companion Animal Safety	45620507	Merial	Pay	
Signature 		Name and Title David Jones Manager Regulatory Affairs		Date Sept. 24, 2013 200	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATA MATRIX

Date	Sept. 24, 2013	EPA Reg. No./File Symbol	2596-	Page 5 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Companion Animal Safety	Waiver requested	Hartz		
40 CFR 157 Subpart B	Child Resistant Package Testing	48684601	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684602	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684603	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684604	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684605	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684606	Hartz	Own	
870.4100	Acute Toxicity, Chronic toxicity	42178309	Sumitomo	FOR	
Signature			Name and Title David Jones Manager Regulatory Affairs	Date Sept. 24, 2013	



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

LIST OF DATA SUBMITTERS SENT OFFER-TO-PAY LETTERS

(Below information comes from <http://www.epa.gov/opppmsd1/DataSubmittersList/>)

Fipronil (CAS 120068-37-3)

S-Methoprene (CAS 65733-16-6)

Merial Limited

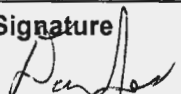
3239 Satellite Blvd.
Bldg. 500
Duluth, GA 30096



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date Sept. 24, 2013		EPA Reg. No./File Symbol 2596-		Page 1 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Hartz	Own	
			Hartz	Own	
Signature 			Name and Title David Jones Manager Regulatory Affairs		Date Sept. 24, 2013 203



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date Sept. 24, 2013		EPA Reg. No./File Symbol 2596-		Page 2 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Self-certification	
			Hartz	Self-certification	
Hartz	Self-certification				
Signature <i>David Jones</i>			Name and Title David Jones Manager Regulatory Affairs		Date Sept. 24, 2013 204



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Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Self-certification	
			Hartz	In progress	
			Hartz	Own	
			Hartz	In progress	
			Hartz	Own	
Signature <i>David Jones</i>			Name and Title David Jones Manager Regulatory Affairs		Date Sept. 24, 2013 205



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DATA MATRIX


Date Sept. 24, 2013		EPA Reg. No./File Symbol 2596-		Page 4 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094-3688		Product Hartz Reference #144			
Ingredient Fipronil/ (S)-Methoprene/ Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Merial	Pay	
			Waiver		
			Merial	Pay	
			Hartz	Own	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
Signature 			Name and Title David Jones Manager Regulatory Affairs		Date Sept. 24, 2013



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz		
			Hartz	Own	
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			Hartz	Own	
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			Hartz	Own	
			Hartz	Own	
Signature 			Name and Title David Jones Manager Regulatory Affairs		Date Sept. 24, 2013 207



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

CHILD RESISTANT PACKAGING CERTIFICATION STATEMENT
Title 40 part 157 subpart B

Registrant Name and Address:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Products:

Hartz Reference # 144, EPA Reg. No. 2596-

I certify that the packaging that will be used for the products listed above meet the standards of 40 CFR 157.32.

A handwritten signature in cursive script, reading "Sean McNear", written over a horizontal line.

Sean McNear
Sr. Director Regulatory Affairs
& Quality Assurance

A handwritten date "April 29, 2013" written in cursive script over a horizontal line.

Date

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%

OTHER INGREDIENTS	78.15%
--------------------------------	---------------

TOTAL	100.00%
--------------------	----------------

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 Weeks and older weighing 3lbs. or more.

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-275-1414 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

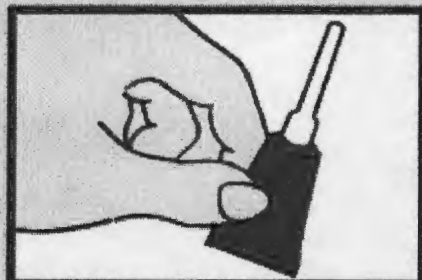
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

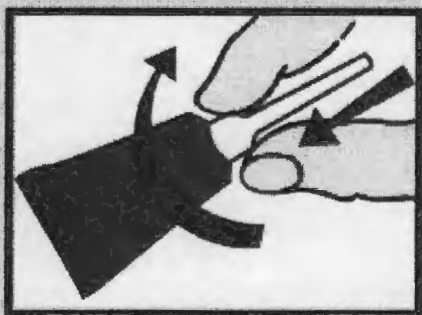
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS.**

DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

Prevents establishment of new infestations after application in the home environment

Prevents establishment of new infestations after application on premises

Prevents establishment of new infestations in the home environment

Prevents establishment of new infestations on premises

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults in the home environment (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults (on premises) (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation in the home environment

Dual insect growth regulator (IGR) technology prevents re-infestation

Dual insect growth regulator (IGR) technology prevents re-infestation on premises

Contains two unique ingredients to prevent flea infestations

Contains two unique ingredients to prevent flea infestations in the home environment

Contains two unique ingredients to prevent flea infestations on premises
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Effective after bathing
Effective after exposure to water
Patents Pending
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

New (Formula) (*claim to be removed after 6 months*)

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more
Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose
First month, second month, third month
Value pack
3 month supply
3 monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your cat 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____
Second Dose _____
Third Dose _____

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Nylar® - Registered Trademark of McGlaughlin Gormley King Company

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